LEGISLATIVE BUDGET AND FINANCE COMMITTEE

A JOINT COMMITTEE OF THE PENNSYLVANIA GENERAL ASSEMBLY

A Report in Response to HR 1087 of 2020 COVID-19 Death Reporting

November 2021

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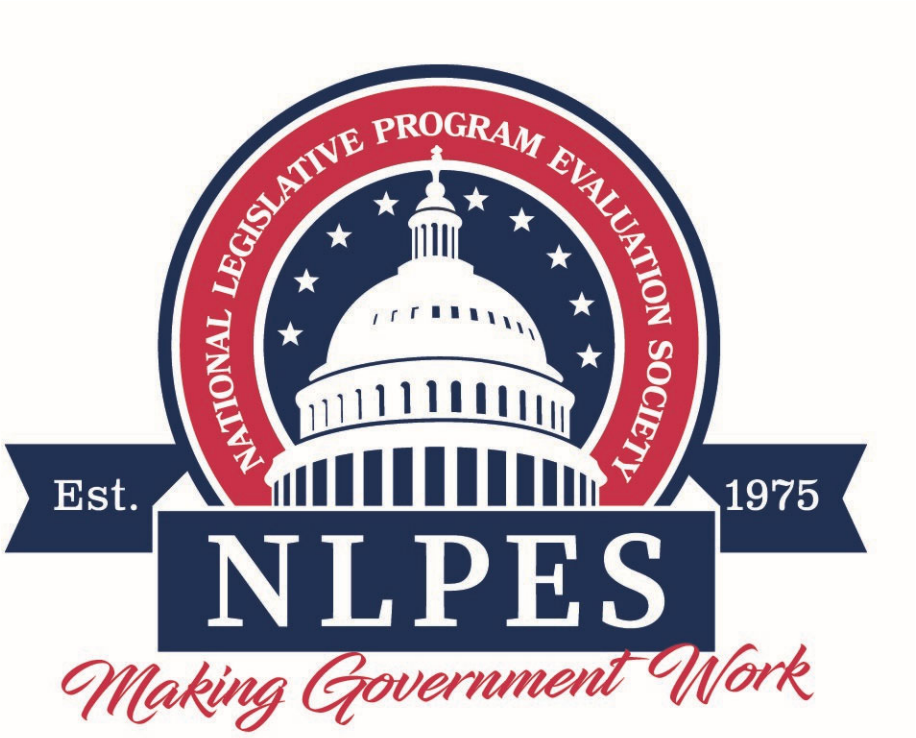

For the sixth straight year the National Legislative Performance Evaluation Society (NLPES) awarded the Legislative Budget and Finance Committee with a Certificate of Impact. The Certificate of Impact is presented to legislative offices that produce evaluations or audit reports that resulted in documented public policy changes, program improvements, dollar savings or other public impacts.

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REPORT SUMMARY

Objectives and Scope

As adopted by the LBFC's Officers, our objectives for this specific study were briefly the following:

1. *Review death certificates for citizens who may have died from COVID-19 to ensure the deaths were properly, accurately, and consistently reported to DOH.*

2. *Identify any possible areas for improvement.*

The scope of our review was for deaths occurring in calendar year 2020. Our access to death certificates/records was denied by DOH; consequently, we have issued a scope limitation and impairment.

Report Overview

On November 19, 2020, the Pennsylvania House of Representatives adopted House Resolution (HR) 1087, which requested the Legislative Budget and Finance Committee (LBFC) to conduct a series of studies on issues surrounding the COVID-19 pandemic (see Appendix A). These studies are to be released on a rolling basis and continue until 90 days after the Governor's emergency declaration ends.

Our work is primarily focused on the Pennsylvania Department of Health (DOH) and its collection and reporting of specific data related to the COVID-19 pandemic. This report focuses on COVID-19 death reporting.

As discussed later in Section IV, because DOH denied us access to review death certificates[1] and the underlying death records, this report contains a scope limitation and impairment.

Our report is divided into four sections:

I. Introduction, Scope, and Objectives.
II. Background Information About Vital Records.
III. Death Reporting.
IV. Review of COVID-19 Death Records.

Except for the first section, which is summarized above, each of these sections and the resulting issue areas are summarized through the following pages.

[1] With respect to terminology used in this report, we use the term "death certificate" in its common meaning—an official documentation of death. Most people are familiar with this term, and it is used commonly by researchers and other professionals. However, technically speaking, and as used by the Department of Health, a death certificate is a legal document issued on specialized security paper that contains a raised seal. The Department of Health (or local registrars) issue a death certificate from an underlying "death record," which is created from a "death report" that closely mirrors the death certificate. The death report is initiated electronically (or by paper means) by mandated reporting authorities. Death records are maintained in perpetuity by the Department of Health.

Background Information About Vital Records

Vital records cover a variety of life events, such as birth, marriage, and for purposes of this report, deaths. Vital records are an important tool in developing public health policy, as well as tracking social evolution.

Pennsylvania attempted to create a statewide register of vital records as early as 1852, however, the law was repealed three years later due to a lack of compliance. Pennsylvania did not adopt a permanent statewide death registry until 1906. In that year, DOH was formally established and subsequently began to issue birth and death certificates.

The formalization of vital statistic reporting and record keeping continued with the Vital Statistics Law of 1953 (VSL). The VSL empowered DOH with the collection, verification, and publication of records. For example, section 501 of Article V required a "certificate of death" to be filed within four business days of death. Furthermore, the law cemented the mandatory roles various players have in the death recording process, including funeral directors, medical professionals, coroners, and medical examiners.

More recently, technology has played a significant role in the manner of reporting deaths by moving away from a paper-based system to an electronic system that streamlined the reporting process. Known as the Electronic Death Registration System (EDRS), Pennsylvania was slow in developing this system, but as explained in Section III, mandated its use for COVID-19 death reporting.

With respect to death reporting, most people may be familiar with a death certificate, which is an official legal document, issued under governmental seal. A death certificate declares the cause of death, location of death, time of death, and other personal information. Death certificates are a necessary document that is used to settle an individual's estate, access certain public or private benefits, and allow a widow/widower to remarry.

Although the federal government requires death registration data, the process is a state function, supported by state laws and regulations. In Pennsylvania, as previously mentioned, the VSL mandates the reporting process within a designated timeframe (four days). While the death registration process is a state responsibility, each state has a contract with the Centers for Disease Control and Prevention's, National Center for Health Statistics (CDC/NCHS) that allows the federal government to use information from state records to produce national vital statistics. The national data program is called the National Vital Statistics System (NVSS) and is the official tabulation and analysis of all deaths in the United States.

Within Pennsylvania, there is a complex relationship between funeral directors, medical professionals, coroners, and medical examiners. Each party has unique responsibilities in the death reporting process. Beyond these groups, there are also local registrars, who are appointed by DOH and work under the direction of the State Registrar, to work with funeral directors to register deaths that occur in Pennsylvania.

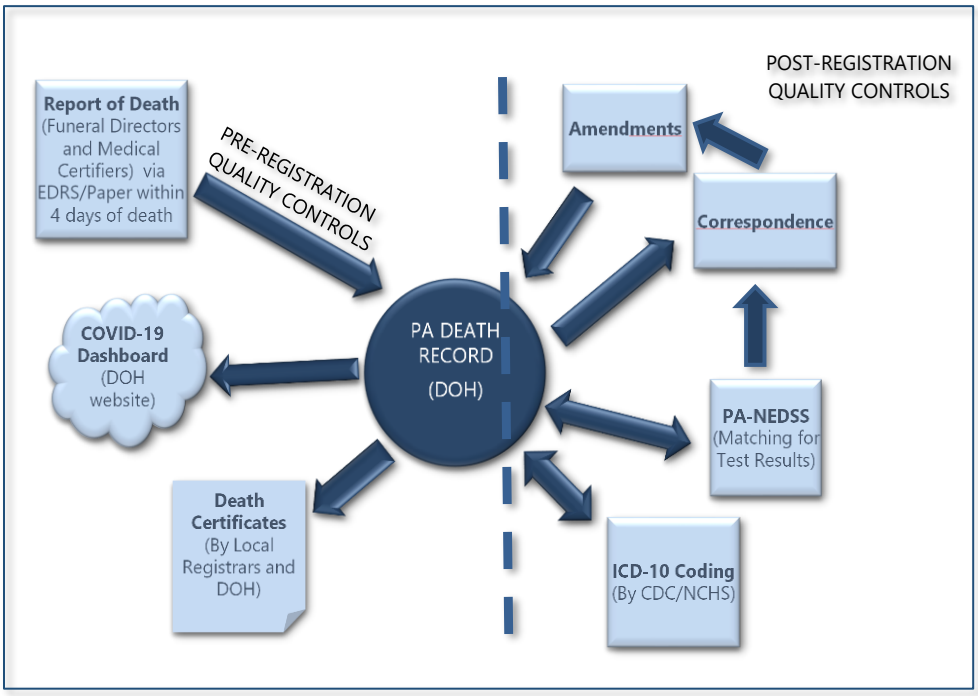
Staff from the DOH's Bureau of Health Statistics and Registries also play a critical role in managing death records. Of particular importance, this bureau is responsible for identifying and logging COVID-19 deaths, which are later reported on the state's COVID-19 dashboard. Beyond COVID-19 reporting responsibilities, the bureau is primarily responsible for regulating the vital events reporting process, for registering vital events, for maintaining vital records created from the registered reports, for issuing certificates on vital events, and for publishing data surrounding vital events.

Section III – Death Reporting

Within this section we discuss five contextual issues surrounding death reporting generally, and COVID-19 death reporting specifically. **First**, was the roll out of Pennsylvania's Electronic Death Registration System (EDRS). This system offers many improvements over a paper-based process, but the system was not fully in use prior to the pandemic. In March 2020, as the pandemic began to take hold in Pennsylvania, DOH mandated that all deaths from COVID-19 be reported through EDRS. This mandate was intended to speed up the accuracy and reporting of COVID-19 deaths. Prior to this mandate, a paper system was the primary means of reporting deaths.

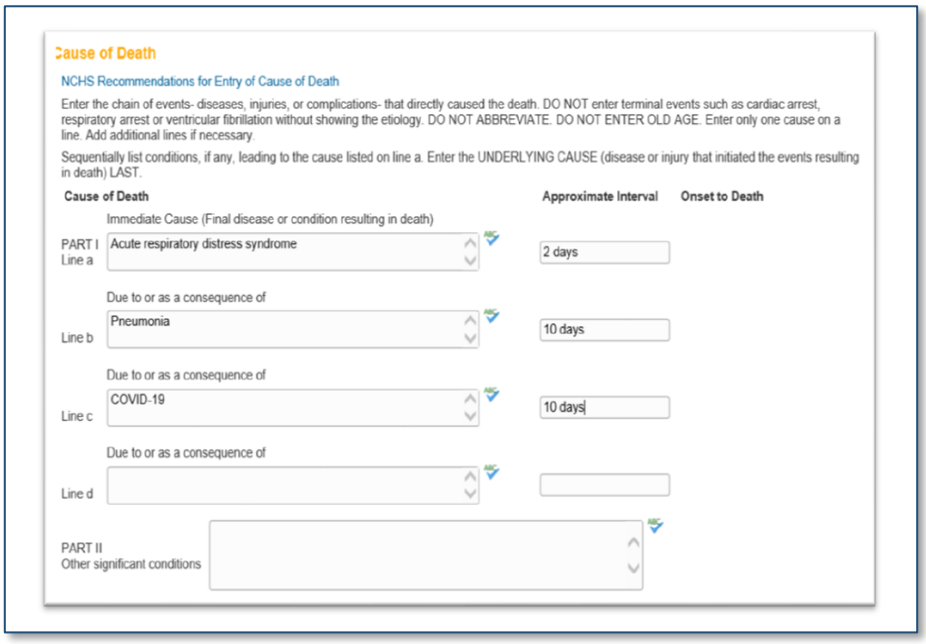
Second, and closely related to the first, is the timeliness in reporting and registering deaths. As shown in figure 1, the death record workflow is complicated and allows for amendments to the records after registration.

Fig. 1: Death Record Workflow



Reporting a death generally means that the death has occurred, and a funeral director or certifier has started the data collection process, whether it be through EDRS or a paper-based process. Conversely, *registering* a death means that the death report is complete, signed by all parties, and has been accepted by DOH. DOH only reports data on registered COVID-19 deaths, which are then sent to the Centers for Disease Control and Prevention and its affiliate the National Center for Health Statistics (CDC/NCHS), where final medical coding is completed. Further, while DOH reports registered COVID-19 deaths daily, these figures are still considered to be provisional; thus, the numbers are subject to change based on amendments to the original death record. In addition, there are multiple federal, state, and local entities that report COVID-19 deaths; however, not all these sources are providing uniform and consistent reports. For example, DOH's website presents an abundant amount of data on long-term care facilities (i.e., skilled nursing facilities, assisted living, and personal care homes) but most of this data is self-reported, minimally verified for completeness, and obtained from sources other than death certificates. In the end, users are left with a baffling amount of data, but no linkage to its meaning or source, which leaves many end users questioning the accuracy of information presented.

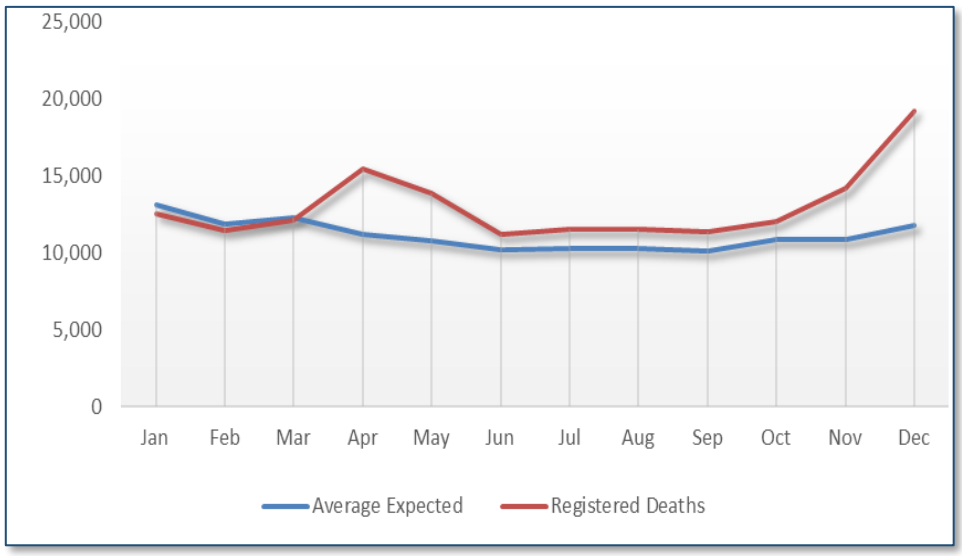
Fig. 2: Sample COD Reporting in EDRS



Third, is decoding and understanding the meaning of "cause of death" (COD) statements and how this information is used to identify deaths from COVID-19 (see figure 2). COD as reported on a death certificate consists of two parts. Part I focuses on the chain of events causing death. This chain of events consists of three events: (1) the *immediate* cause of death; (2) the *intermediate* cause of death; and (3) the *underlying* cause of death. Part II focuses on the significant health conditions, also known as comorbidities, that contributed to the death, but are not included in the sequence of events listed in Part I. COD is determined by a medical certifier based on their medical training and judgment, but it is <u>not</u> a definitive conclusion about the death. In Pennsylvania (as in many states), COD reporting is often incomplete or is unsuitable for medical coding purposes. Research from the CDC/NCHS revealed that in 2018, across all states, 34.7 percent of all death records had an "unsuitable" COD. In Pennsylvania, the unsuitability of COD statements was 39.9 percent, worse than the national average. It is important to underscore that an illogical or non-conforming COD sequence does NOT mean the death report is wrong; rather, it means that sequence of death did not follow an appropriate sequence for medical coding purposes.

Fourth, with respect to COVID-19 deaths, COD statements are used as the basis for reporting death counts from the disease. Each state may use a slightly different process for counting a COVID-19 death, which can raise questions about whether a decedent died *from* COVID-19 or *with* COVID-19 and how to count these deaths. DOH uses criteria established by the CDC/NCHS and counts a COVID-19 death as one where COVID-19 is listed anywhere on Part I or Part II of the death certificate. DOH guidance issued to medical certifiers states that if COVID-19 did not directly cause or contribute to a death, it should not be included on the death report; therefore, it is assumed that if COVID-19 appears on a death report it caused or contributed to the death. DOH counts deaths where COVID-19 has been confirmed by laboratory testing, or where COVID-19 is presumed to be a cause based on clinical factors.

Fig. 3: "Excess Deaths" in 2020



Finally, as a means of providing additional perspective about death reporting, as shown in figure 3, we also reviewed a concept known as "excess deaths." This calculation compares the number of expected deaths to the number of actual registered deaths for a certain period. We obtained expected deaths from the CDC/NCHS and compared it to the registered (provisional) deaths that occurred in calendar year 2020. As shown above, in 2020 Pennsylvania had 22,725 excess deaths, or approximately 17 percent more than what would be expected in a "normal" year. We caution that not all these excess deaths are directly attributable to COVID-19.

Section IV – Review of COVID-19 Death Records

As guided by HR 1087 our intent was to review death certificates/records for individuals who had COVID-19 listed on their death record. While the information we sought is generally confidential under the state's 1953 Vital Statistics Law (VSL), the VSL provides exceptions to that confidentiality. The VSL allows DOH to share the information with government agencies and permits the use of the information for research. DOH denied our request. DOH has taken the position that our request fell outside the allowed statutory exceptions because DOH made the legal conclusions that: (1) the LBFC is not an "agency of government;" (2) our work is not "in the interest of conduct of official duty;" and (3), our work in studying and analyzing the reporting of death records in the Commonwealth is not "research."

We strongly disagree with DOH's position on each of these points and presented an alternative interpretation of the law with which DOH disagrees (see Appendices B and C). We continue to be in discussions with DOH over access to this information, and we will revisit the issue in future reports. In the interim and for this specific report, we have issued a

scope limitation because DOH's denial of access to source documentation (i.e., death records) impairs our ability to answer the objective.

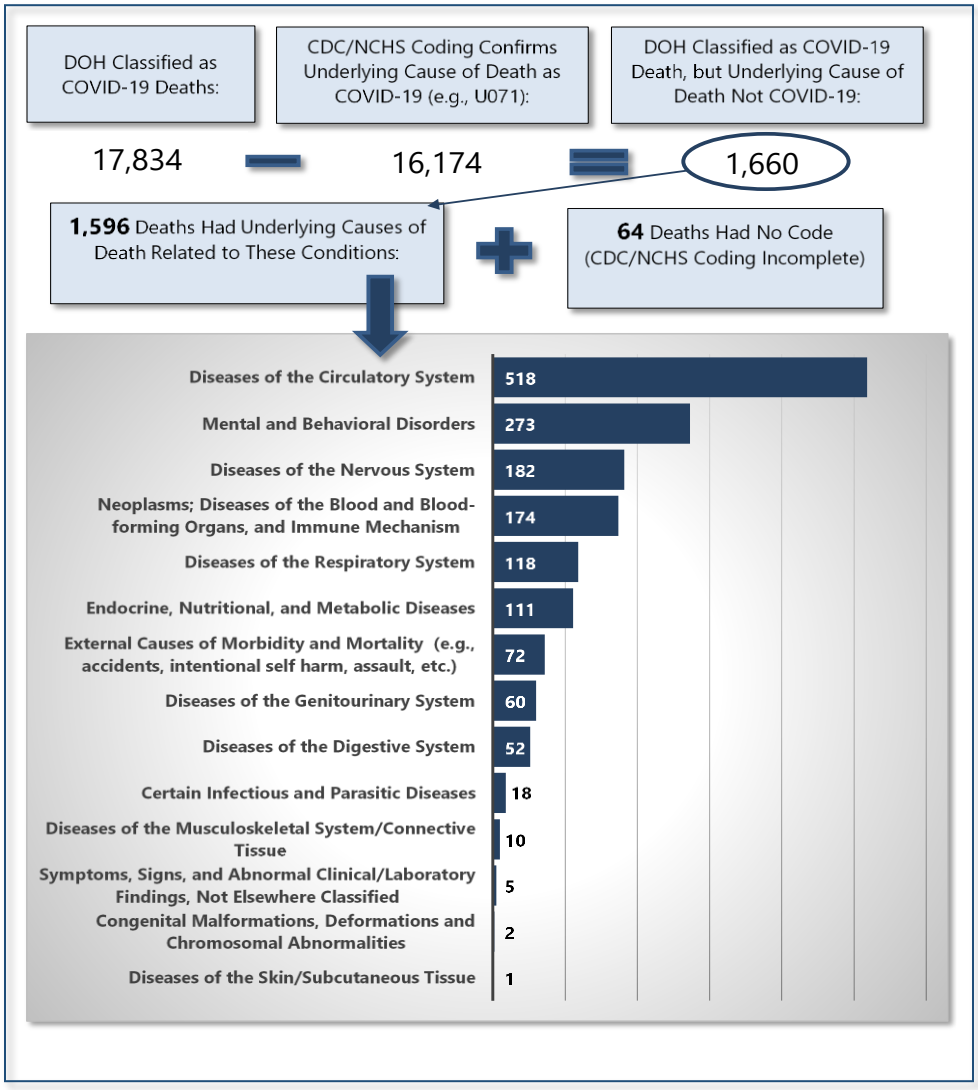
In the interim, we worked with DOH to obtain highly redacted information about COVID-19 deaths. DOH provided us with a data file containing all deaths for which the agency had assigned an internal classification as either COVID-19, COVID-19 Probable, or COVID-19 Probable – Incorrect Terminology. A fourth classification called "COVID-19 Pending Test Results" is also used when the case is believed to be a COVID-19 death, but test results are needed to confirm. These latter cases are not reported as COVID-19 cases until the death record has been amended to indicate the death was attributed to COVID-19. Included with the data file supplied to us was also the CDC/NCHS' determination of the underlying cause of death.

The data file contained 17,834 records for deaths which occurred as of December 31, 2020. Of that number, the overwhelming majority (98 percent) had been internally classified as "COVID-19" deaths. Fewer than two percent were assigned as "COVID-19 Probable," and very few—approximately 0.2 percent - were assigned "COVID-19 Probable – Incorrect Terminology."

Our only source of corroborating evidence for these deaths (as well as a source for additional demographic detail) was from DOH's Weekly Report of COVID-19 Deaths. We used this report, as of December 31, 2020, as a basis for demographic information about COVID-19 deaths. This report, however, contains 15,978 records. The difference between this report and the data file supplied to us is due to the timing between when the reports were generated, and according to DOH, information contained in the death record when data was supplied. In terms of demographic detail, the weekly report showed that nearly 58 percent of COVID-19 deaths were among those aged 80 and older, with the largest frequency of deaths occurring among those aged 85-89.

Lastly, with respect to the 17,834 records we received from DOH, we further reviewed that data file and found that 1,596 records had been coded by the CDC/NCHS with an underlying cause of death as something other than COVID-19. This fact does not mean that the deaths were not to be counted as COVID-19 deaths. Rather, we believe the discrepancy is explained by how deaths are counted. For disease surveillance purposes (and per CDC/NCHS guidance) DOH counts COVID-19 deaths broadly, i.e., "COVID-19" appearing anywhere on Part I or Part II of the death certificate. However, the data DOH supplied to us from the CDC/NCHS, is just the underlying cause of death as determined from Part I of the death certificate. This problem is akin to the issue of trying to count deaths dying *with* COVID-19 and/or dying *from* COVID-19.

Fig. 4: Summary of Death Records Provided to LBFC



We would have reviewed these records closer to determine if in fact our conclusion was correct and investigate any other anomalies, but without access to the corresponding death certificates and records we can only provide limited analysis. For example, of the 1,596 records that did not have COVID-19 as an underlying cause of death, 518 were related to diseases of the circulatory system. Our analysis is summarized in figure 4.

Recommendations

Our report includes three recommendations:

1. **DOH needs to improve its data collection and presentation on its website**. COVID-19 data on DOH's website, while plentiful, needs better descriptions of its source and where and why it may conflict with other presented data sources. Some states, like Oregon, Wisconsin, and Alaska, to name three specific examples, provide detailed descriptions of where death data is collected, how the collection process works, and why fluctuations may be apparent. Wisconsin includes YouTube videos with relevant state experts explaining the details of its data collection and reporting procedures. DOH needs to improve upon its data definitions and in clear terms explain the significance of the data to end-users. Further, and most importantly, DOH needs to resolve the inconsistent reporting that is apparent in long-term care facility data.

2. **DOH should monitor the accuracy in cause of death reporting through, in part, the creation of a task force of stakeholders to address ongoing issues**. Cause of death reporting was an issue area prior to the pandemic. Since the pandemic, the need for accurate COD reporting has been emphasized. DOH should form and lead a taskforce of stakeholders, which at a minimum would include representatives of coroners, physicians, funeral directors, and medical schools. The taskforce should work to identify a plan to address issues including, but not limited to, the following:

    a. Communication barriers between parties involved in preparing death records.
    b. Information technology solutions and best practices.
    c. Curriculum enhancements for medical professionals on death reporting/cause of death reporting.
    d. Need for continued education training opportunities for medical certifiers and others on death reporting.
    e. Development of a "data quality" team to semi-annually monitor the suitability of cause of death reporting in Pennsylvania.

3. **The General Assembly should consider amending the Vital Statistics Law to expressly grant access to the records to legislative agencies**. To avoid any future confusion, the General Assembly should consider amending the Vital Statistics Law to expressly grant legislative service agencies access to all vital record information as needed to conduct authorized research and studies.

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SECTION I
OBJECTIVES, SCOPE, AND METHODOLOGY

Why we conducted this study…

- *House Resolution (HR) 1087 was adopted on November 23, 2020, by the House of representatives. HR 1087 focused on data reporting related to the COVID-19 pandemic.*
- *To answer the objectives of HR 1087, the Officers adopted a phased report. This approach involves releasing periodic reports on aspects related to the Department of Health's reporting of COVID-19 data.*
- *This first report focuses on the death reporting process in Pennsylvania, specifically the reporting of deaths from COVID-19. Future reports will be issued until the Governor's emergency declaration expires.*

Introduction

While certain years are more memorable than others, 2020 was an especially historic year. Primary among the many notable events was the COVID-19 pandemic—a condition which led Governor Wolf to declare a state-wide disaster emergency in March 2020. The pandemic is likely to continue to have a severe impact on the Commonwealth well into 2021 and beyond.[2]

In response to this condition, on November 19, 2020, the Pennsylvania House of Representatives adopted House Resolution (HR) 1087, which requires the Legislative Budget and Finance Committee (LBFC) to conduct a series of studies on issues surrounding the pandemic (see Appendix A).

These studies are to be released every 90 days and end 90 days after the Governor's emergency declaration ends. As a result of a recently passed voter referendum, that declaration has ended pending certification of the 2021 primary results by the Department of State.

Finally, with respect to terminology used in this report, we use the term "death certificate" in its common meaning—an official documentation of death. Most people are familiar with this term, and it is used commonly by researchers and other professionals. However, technically speaking, and as used by the Department of Health, a death certificate is a legal document issued on specialized security paper that contains a raised seal. The Department of Health (or local registrars) issue a death certificate from an underlying "death record," which is created from a "death report" that closely mirrors the death certificate. The death report is initiated electronically (or by paper means) by mandated reporting authorities. Death records are maintained in perpetuity by the Department of Health.

[2] Throughout this report when using the term pandemic, we are referring to the pandemic caused by the novel coronavirus, which was first identified in China in December 2019.

Objectives

After a House or Senate resolution is adopted, as a matter of practice the LBFC's Officers also adopt objectives for the proposed study. Study objectives allow us to answer the requirements of the resolution more precisely, while also providing an outline from which to guide and plan the various study phases.

As directed by the officers of the LBFC, on November 23, 2020, the following objectives were approved:

1. Conduct a review of the number and type of COVID-19 tests completed in the Commonwealth.

2. Review the policies, procedures, and practices for reporting COVID-19 test results to the DOH and to the Centers for Disease Control and Prevention.

3. Review death certificates for citizens who may have died from COVID-19 to ensure the deaths were properly, accurately, and consistently reported to DOH.

4. Identify any possible areas for improvement for DOH and its reporting of COVID-19 data including test results, cases, and deaths.

For This Report

As mentioned, HR 1087 requires a series of reports that are to continue while the Commonwealth is under the emergency declaration. Under this approach, the LBFC Officers have adopted a phased report release structure. To that end, this report is the first report to be released and covers only objectives three and four, regarding COVID-19 death reporting.

Scope

According to Government Auditing Standards, issued by the Comptroller General of the United States through the Government Accountability Office (GAO), scope refers to the boundary of a study and is directly tied to the audit objectives. Scope defines the subject matter that will be re-

ported on, such as a particular program or aspect of a program, the necessary documents or records, the period reviewed, and the locations that will be included.[3]

As outlined in HR 1087, the scope, or period to be reviewed, for this study was defined as March 6, 2020 (the date of the Governor's original emergency declaration), through March 6, 2021, or 90 days after the Governor's emergency declaration. For purposes of this report, our review period was March 6, 2020, through December 31, 2020.

Scope Limitation and Impairment

As explained in Section IV, DOH denied us access to information that we believe necessary to fully address the objectives. Specifically, we were denied access to death certificates (the underlying product of the registered death record). For this reason, we have issued a "scope limitation and impairment" for our results and conclusions contained within our review of DOH data. The COVID-19 death data we received was supplied to us by DOH, and because DOH denied us access to certain information, we could not corroborate the data or trace it to source documentation to verify its authenticity.

Methodology

We conducted extensive research on vital statics and reporting. We obtained this research from experts in the field, including the Centers for Disease Control (CDC). We also interviewed the head of the federal government's mortality statistics branch within the National Center for Health Statistics (NCHS).

We spoke with representatives from the Pennsylvania Coroners' Association about the death certification and reporting process, as well as the use of the state's Electronic Death Reporting System (EDRS).

We reviewed guidance from the CDC/NCHS on death certification. We completed training given by the CDC/NCHS on the proper procedures for certifying a cause of death, including Part I and Part II of a death certificate. We also completed CDC/NCHS training and guidance on COVID-19 cause of death reporting. We supplemented this training with information obtained from the CDC's *Physicians Handbook on Medical Certification of Death*, as well as guidance published by the College of American Pathologists.

[3] *See* Comptroller General of the United States, Government Accountability Office, Government Auditing Standards, 2018 revision, paragraph 8.10.

We interviewed the State Registrar, within the Pennsylvania Department of Health, about Pennsylvania's death registration process and procedures. We also observed the death reporting process for individuals who died from COVID-19.

We spoke with a non-representative sample of funeral directors from across the state. We discussed their opinions about processing COVID-19 death reports, their experiences in dealing with COVID-19 deaths, as well as their experiences using EDRS. We also surveyed a limited sample of medical providers about their use of EDRS.

We obtained data on COVID-19 deaths from DOH's website. We reviewed data from Pennsylvania's COVID-19 dashboard, data related to long term care facilities, as well as other data sources that DOH published periodically on its website. We compared these data sources to corroborate numbers presented from other reporting sources, including the CDC/NCHS (COVID Data tracker), county coroners, and self-reported information by facilities.

We reviewed research conducted by the CDC/NCHS on the unsuitability of underlying cause of death. We discussed the results of the research with the study's authors and sought their opinions about the accuracy of cause of death reporting, as well as Pennsylvania's performance generally.

We reviewed other states' websites for examples of how other states explain the death registration and reporting processes. We spoke with representatives from Washington State about its COVID-19 death reporting process, and the data quality controls used there. We also reviewed data reliability concerns published by the *COVID-19 Tracking Project,* a volunteer organization launched from *The Atlantic*.

We obtained data from DOH on how it "internally classified" deaths attributed to COVID-19. We obtained all provisional deaths from COVID-19 by these internal classifications. We also obtained the CDC/NCHS' medical code assigned to these deaths. We looked up the non-COVID-19 codes to determine what the underlying cause of death was in medical terminology. We also performed various sorts and counts on this data.

Frequently Used Abbreviations and Definitions

Throughout this report, we use several abbreviations for government-related agencies, terms, and functions. These abbreviations are defined as follows:

Abbreviation	Name	Definition
DOH	Department of Health	Pennsylvania state agency which promotes healthy behaviors, prevents injury and disease, assures the safe delivery of quality health care for all people in the state
CDC	Centers for Disease Control and Prevention	National agency headquartered in Atlanta, Georgia tasked with surveilling and studying public health areas of concern
NCHS	National Center for Health Statistics	Federal vital statistics data collection agency located under the CDC.
EDRS	Electronic Death Registration System	Web-based application that simplifies the data reporting process while increasing data quality and supports the rapid-reporting of deaths that occur in Pennsylvania.
AMA	American Medical Association	Founded in 1847, the AMA is the largest association and lobby for physicians and medical students in the United States
VSL	Vital Statistics Law of 1953	Pennsylvania's enabling statute covering vital statistics and recordkeeping.
NVSS	National Vital Statistics System	Intergovernmental system of sharing data on the vital statistics of the population of the United States; headquartered in Hyattsville, MD.
BHSR	Bureau of Health Statistics and Registries	Subdivision of DOH, BHSR manages several public health registries that collect data. Registries include vital events such as birth, death, and fetal death
ICD	International Classification of Diseases	Diagnostic tool established by WHO to classify and monitor causes of illness and death to study mortality and morbidity trends
NEDSS	National Electronic Death Surveillance System	Web based system of electronically transferring public health surveillance data from the healthcare system to public health departments.
COD	Cause of Death	Determined by a medical certifier, the cause of death is an official record of the conditions leading to one's death. COD captures medical conditions that occur within Part I of the death certificate.
WHO	World Health Organization	Specialized agency of the United Nations responsible for monitoring and promoting international public health.
U07.1	Confirmed COVID-19 Case	ICD classification for lab confirmed case of COVID-19
U07.2	Probable COVID-19 Case	ICD Classification for unconfirmed but probable case of COVID-19

LTCF	Long Term Care Facility	A generic term that in Pennsylvania includes skilled nursing facilities, personal care homes, and assisted living facilities.
SNF	Skilled Nursing Facility	Facilities that provide high level of medical care by licensed health professionals, such as registered nurses and physical, speech, and occupational therapists.
CMS	Centers for Medicare and Medicaid Services	Federal agency under the US Department of Health and Human Services that with state governments manages provisions of the Medicare and Medicaid programs.
DHS	Department of Human Services	Pennsylvania state agency tasked with providing care and support to Pennsylvania's most vulnerable individuals and families.

Acknowledgements

We thank Alison Beam, Acting Secretary, and the staff of the Pennsylvania Department of Health, including especially Mr. Peter Blank, Director of Policy, and Ms. Audrey Marrocco, State Registrar. Their insights and assistance were instrumental in allowing us to obtain the information contained in the report. We also thank the representatives from the Pennsylvania Coroners' Association, the Centers for Disease Control and Prevention, and the funeral directors who spoke with us, for their input and assistance.

Important Note

This report was developed by the staff of the Legislative Budget and Finance Committee, including project manager Stephen Fickes and staff analyst Rebanta Mukherjee. The release of this report should not be construed as an indication that the Committee as a whole, or its individual members, necessarily concur with the report's findings, conclusions, or recommendations.

Any questions or comments regarding the contents of this report should be directed to the following:

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SECTION II
BACKGROUND INFORMATION ABOUT VITAL RECORDS

Fast Facts…

- *Vital records cover a variety of different life events, such as birth, marriage, and for purposes of this report, deaths. Vital records are an important tool in developing public health policy, as well as tracking civilization's evolution.*
- *Deaths are recorded on a certificate of death reporting form. Death certificates are used to close out a decedent's estate, while death record data is transmitted to the federal government for producing national vital statistics.*
- *Death reporting requires coordination between funeral directors and medical certifiers. Funeral directors report demographic information, and medical certifiers pronounce death and establish cause of death.*

Introduction

Tracking significant life events, such as births, deaths, and marriages has been a societal practice for hundreds of years. Most modern civilizations record these events as vital records, and when these records are collectively analyzed, the results provide insight and observable trends for doctors, public health experts, social scientists, and policy makers. In turn, these records provide support for the development of new laws, as well as for developing an understanding of critical public health issues, all of which further civilization's advancement. Within this section, we present contextual information about vital records and death reporting. This information supplements the discussions that follow in later sections of the report.

Historical Perspectives

While many civilizations conducted periodic census counts, these events were more for the purposes of taxation or the availability of military manpower. Many historians agree that birth records were formally introduced in England, however, these records were collected and kept by religious authorities, not governmental authorities, and as result there was little uniform structure in how the events were recorded and maintained.

Birth and Death Records

Early American colonists who came from England were accustomed to the recording of church-related events such as christenings. Therefore, in 1632 the Grand Assembly of Virginia legally convened an annual presentation of these events, which translated into recording births to ensure individual rights, primarily for property. In 1639, Massachusetts took the next step requiring the government to record these vital events, rather than clergy recording baptisms.[4]

[4] H.L. Brumberg, "History of the Birth Certificate: from inception to the future of electronic data," *Journal of Perinatology*. February 2012.

The 1800s led to high rates of immigration to the Northeastern United States. Urban dwellers, especially the poor, lived in crowded, unsanitary conditions, exacerbated by pollution produced by rapid industrialization. In response, sanitary reformers used scientific approaches to develop data-driven solutions, thereby emphasizing the importance of collecting systematic vital records of births and deaths. Furthermore, birth registration could be used to monitor public health interventions.[5]

The prototype for American state-based registration was created after a cholera epidemic engulfed England and Wales prompting British reforms such as the maintenance of vital records through a single office in 1836. This inspired the first American state registration law enacted in Massachusetts in 1842. The American Medical Association (AMA) then supported the movement toward better vital records by creating a committee to analyze the methodology of vital records registration in 1846. However, even as other states or cities followed suit, no uniformity of data collection was put in place.[6]

Pennsylvania Perspectives

Pennsylvania attempted to create a statewide register of vital records in 1852, however, the law was repealed just three years later due to a lack of compliance. Pennsylvania did not adopt a permanent statewide death registry until 1906. In that year, the Pennsylvania Department of Health (DOH) was formally established and subsequently began to issue birth and death certificates. By 1933, all states were registering live births and deaths with acceptable event coverage and providing the required data to the Bureau of Census to produce national birth and death statistics.

Vital Statistics Law of 1953

Pennsylvania took a significant step toward standardizing death reporting with the passage of the Vital Statistics Law in 1953 (VSL). The VSL empowered DOH with administering the VSL. Furthermore, the law cemented the mandatory roles various players have in the death recording process, including funeral directors, medical professionals, coroners, and medical examiners.

[5] Ibid.
[6] Ibid.

Electronic Death Registration System

As technology has improved significantly over the years, so too has the need for more timely and accurate death reporting. As early as 2003, the National Vital Statistics System (NVSS) began shifting from paper-based reporting to electronic systems. However, these electronic systems were mostly individual and because the jurisdiction for vital record keeping remained with the states, the federal government lacked any enforcement mechanism to mandate states to transition to a paperless system.

DOH began its formal transition to electronic reporting for deaths with the Electronic Death Registration System (EDRS) in 2016.[7] Per DOH's website, EDRS is a web-based application that simplifies the data reporting process while increasing data quality and supports the rapid-reporting of deaths that occur in Pennsylvania. EDRS is available to funeral directors and medical certifiers, including coroners, medical examiners, and medical professionals who are responsible for certifying deaths. EDRS is designed so that support staff may complete most of the data entry into the system. As discussed later in Section III, EDRS was an important factor in how DOH addressed death reporting for deaths attributed to COVID-19.

Understanding Death Reporting

All deaths are formalized on a death record. Information on the death report may be submitted electronically, as in the case of EDRS, or it may be manually keyed from information collected on medical certification worksheets. The death certificate is an official legal document, issued under governmental seal, which declares cause of death, location of death, time of death, and other personal information, as known to the medical certifier and funeral director. Death certificates are a necessary document used to settle an individual's estate, access certain public or private benefits, and allow a widow/widower to remarry. Generating and creating death records involves a complex coordination between various mandated reporting parties. Within this section, we will discuss the death certificate/record as well as the various reporting authorities at the local, state, and federal levels.

Death Certificate/Record

Although the federal government requires death registration data, registering deaths is a state function, supported by state laws and regulations.

[7] Note: According to DOH, funding for EDRS actually began in FY 2009-10.

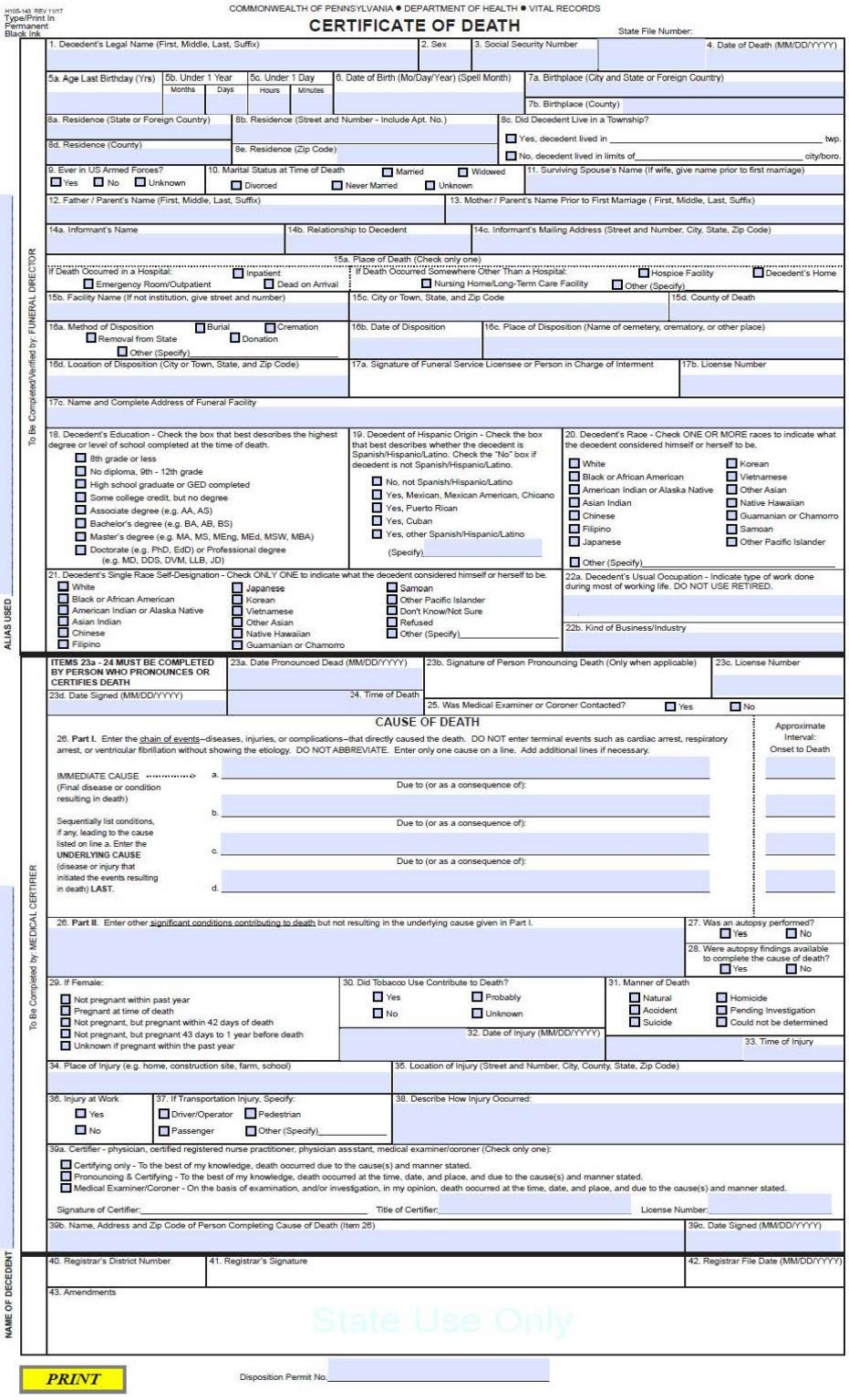
In Pennsylvania, as previously mentioned, the VSL mandates the reporting and timeliness of the death reporting process. While the death registration process is a state responsibility, each state has a contract with the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) that allows the federal government to use information from state records to produce national vital statistics. The national data program, National Vital Statistics System (NVSS), is responsible for the official tabulation and analysis of all deaths in the United States.

To ensure consistency in data reporting, the NCHS provides leadership in the development of a standard death certificate (US Standard Certificate of Death reporting form) for all states to use as a model. Each state may have slightly different versions of this death certificate model to accommodate any unique state requirements, but for the most part the national model is the standard all states follow. Uniformity in death certificate forms ensures that the data will be comparable from state-to-state for data quality purposes, as well as acceptability for legal purposes.[8] The Pennsylvania standard certificate of death reporting form is shown in Exhibit 1.

[8] CDC, *Physicians' Handbook on Medical Certification of Death*, 2003.

Exhibit 1

Pennsylvania's Certificate of Death (Report) Form



H105-143 REV 11/17
Type/Print In Permanent Black Ink

COMMONWEALTH OF PENNSYLVANIA • DEPARTMENT OF HEALTH • VITAL RECORDS

CERTIFICATE OF DEATH

State File Number:

1. Decedent's Legal Name (First, Middle, Last, Suffix) | 2. Sex | 3. Social Security Number | 4. Date of Death (MM/DD/YYYY)

5a. Age Last Birthday (Yrs) | 5b. Under 1 Year (Months, Days) | 5c. Under 1 Day (Hours, Minutes) | 6. Date of Birth (Mo/Day/Year) (Spell Month) | 7a. Birthplace (City and State or Foreign Country) | 7b. Birthplace (County)

8a. Residence (State or Foreign Country) | 8b. Residence (Street and Number - Include Apt. No.) | 8c. Did Decedent Live in a Township? ☐ Yes, decedent lived in _____ twp. ☐ No, decedent lived in limits of _____ city/boro.

8d. Residence (County) | 8e. Residence (Zip Code)

9. Ever in US Armed Forces? ☐ Yes ☐ No ☐ Unknown | 10. Marital Status at Time of Death ☐ Married ☐ Widowed ☐ Divorced ☐ Never Married ☐ Unknown | 11. Surviving Spouse's Name (If wife, give name prior to first marriage)

12. Father / Parent's Name (First, Middle, Last, Suffix) | 13. Mother / Parent's Name Prior to First Marriage (First, Middle, Last, Suffix)

14a. Informant's Name | 14b. Relationship to Decedent | 14c. Informant's Mailing Address (Street and Number, City, State, Zip Code)

To Be Completed/Verified by: FUNERAL DIRECTOR

15a. Place of Death (Check only one)

If Death Occurred in a Hospital: ☐ Inpatient ☐ Emergency Room/Outpatient ☐ Dead on Arrival

If Death Occurred Somewhere Other Than a Hospital: ☐ Hospice Facility ☐ Decedent's Home ☐ Nursing Home/Long-Term Care Facility ☐ Other (Specify)_____

15b. Facility Name (If not institution, give street and number) | 15c. City or Town, State, and Zip Code | 15d. County of Death

16a. Method of Disposition ☐ Burial ☐ Cremation ☐ Removal from State ☐ Donation ☐ Other (Specify)_____ | 16b. Date of Disposition | 16c. Place of Disposition (Name of cemetery, crematory, or other place)

16d. Location of Disposition (City or Town, State, and Zip Code) | 17a. Signature of Funeral Service Licensee or Person in Charge of Interment | 17b. License Number

17c. Name and Complete Address of Funeral Facility

18. Decedent's Education - Check the box that best describes the highest degree or level of school completed at the time of death.
☐ 8th grade or less
☐ No diploma, 9th - 12th grade
☐ High school graduate or GED completed
☐ Some college credit, but no degree
☐ Associate degree (e.g. AA, AS)
☐ Bachelor's degree (e.g. BA, AB, BS)
☐ Master's degree (e.g. MA, MS, MEng, MEd, MSW, MBA)
☐ Doctorate (e.g. PhD, EdD) or Professional degree (e.g. MD, DDS, DVM, LLB, JD)

19. Decedent of Hispanic Origin - Check the box that best describes whether the decedent is Spanish/Hispanic/Latino. Check the "No" box if decedent is not Spanish/Hispanic/Latino.
☐ No, not Spanish/Hispanic/Latino
☐ Yes, Mexican, Mexican American, Chicano
☐ Yes, Puerto Rican
☐ Yes, Cuban
☐ Yes, other Spanish/Hispanic/Latino (Specify)_____

20. Decedent's Race - Check ONE OR MORE races to indicate what the decedent considered himself or herself to be.
☐ White ☐ Black or African American ☐ American Indian or Alaska Native ☐ Asian Indian ☐ Chinese ☐ Filipino ☐ Japanese ☐ Korean ☐ Vietnamese ☐ Other Asian ☐ Native Hawaiian ☐ Guamanian or Chamorro ☐ Samoan ☐ Other Pacific Islander
☐ Other (Specify)_____

ALIAS USED

21. Decedent's Single Race Self-Designation - Check ONLY ONE to indicate what the decedent considered himself or herself to be.
☐ White ☐ Black or African American ☐ American Indian or Alaska Native ☐ Asian Indian ☐ Chinese ☐ Filipino ☐ Japanese ☐ Korean ☐ Vietnamese ☐ Other Asian ☐ Native Hawaiian ☐ Guamanian or Chamorro ☐ Samoan ☐ Other Pacific Islander ☐ Don't Know/Not Sure ☐ Refused ☐ Other (Specify)_____

22a. Decedent's Usual Occupation - Indicate type of work done during most of working life. DO NOT USE RETIRED.

22b. Kind of Business/Industry

ITEMS 23a - 24 MUST BE COMPLETED BY PERSON WHO PRONOUNCES OR CERTIFIES DEATH

23a. Date Pronounced Dead (MM/DD/YYYY) | 23b. Signature of Person Pronouncing Death (Only when applicable) | 23c. License Number

23d. Date Signed (MM/DD/YYYY) | 24. Time of Death

25. Was Medical Examiner or Coroner Contacted? ☐ Yes ☐ No

To Be Completed by: MEDICAL CERTIFIER

CAUSE OF DEATH

26. **Part I.** Enter the chain of events--diseases, injuries, or complications--that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.

Approximate Interval: Onset to Death

IMMEDIATE CAUSE (Final disease or condition resulting in death)
a. _____ Due to (or as a consequence of):
b. _____ Due to (or as a consequence of):
c. _____ Due to (or as a consequence of):
d. _____

Sequentially list conditions, if any, leading to the cause listed on line a. Enter the **UNDERLYING CAUSE** (disease or injury that initiated the events resulting in death) **LAST**.

26. **Part II.** Enter other significant conditions contributing to death but not resulting in the underlying cause given in Part I.

27. Was an autopsy performed? ☐ Yes ☐ No

28. Were autopsy findings available to complete the cause of death? ☐ Yes ☐ No

29. If Female:
☐ Not pregnant within past year
☐ Pregnant at time of death
☐ Not pregnant, but pregnant within 42 days of death
☐ Not pregnant, but pregnant 43 days to 1 year before death
☐ Unknown if pregnant within the past year

30. Did Tobacco Use Contribute to Death? ☐ Yes ☐ Probably ☐ No ☐ Unknown

32. Date of Injury (MM/DD/YYYY)

31. Manner of Death ☐ Natural ☐ Accident ☐ Suicide ☐ Homicide ☐ Pending Investigation ☐ Could not be determined

33. Time of Injury

34. Place of Injury (e.g. home, construction site, farm, school) | 35. Location of Injury (Street and Number, City, County, State, Zip Code)

36. Injury at Work ☐ Yes ☐ No

37. If Transportation Injury, Specify: ☐ Driver/Operator ☐ Pedestrian ☐ Passenger ☐ Other (Specify)_____

38. Describe How Injury Occurred:

39a. Certifier - physician, certified registered nurse practitioner, physician assistant, medical examiner/coroner (Check only one):
☐ Certifying only - To the best of my knowledge, death occurred due to the cause(s) and manner stated.
☐ Pronouncing & Certifying - To the best of my knowledge, death occurred at the time, date, and place, and due to the cause(s) and manner stated.
☐ Medical Examiner/Coroner - On the basis of examination, and/or investigation, in my opinion, death occurred at the time, date, and place, and due to the cause(s) and manner stated.

Signature of Certifier:_____ Title of Certifier:_____ License Number:_____

39b. Name, Address and Zip Code of Person Completing Cause of Death (Item 26) | 39c. Date Signed (MM/DD/YYYY)

NAME OF DECEDENT

40. Registrar's District Number | 41. Registrar's Signature | 42. Registrar File Date (MM/DD/YYYY)

43. Amendments

State Use Only

PRINT

Disposition Permit No._____

Source: Pennsylvania Department of Health.

As shown on the previous exhibit, the death certificate presents certain demographic data in the top section of the form, including name, address, and birthplace information, but also certain specific information about the decedent, including parents' name, any spouse's name, educational attainment, and ethnicity. The form also captures detailed information on the place of death, the disposition of the body, and the decedent's occupation. All this information is captured in boxes 1 through 22b and is completed by the funeral director (discussed later), who is handling the body.

In the next section of the form, boxes 23a through 24 are completed by the individual who pronounces death. Note that pronouncing death and certifying death are two different steps. In some cases, a physician will both pronounce death and certify the cause of death. Additionally, an inquiry may be required by a coroner (discussed later) to determine a cause of death.[9]

Most important for purposes of this report, the death report requires completion of the "cause of death." The cause of death section is designed to elicit the opinion of the medical certifier. Because causes of death represent a medical opinion, that opinion might vary among individual certifiers. We will discuss the significance of cause of death reporting in Section III; however, for illustrative purposes here, it is merely important to note that this section of the form is completed by a medical professional. More specifically, cause of death reporting meets two requirements. First, it lists the disease or injury that initiated the train of morbid events leading directly to death, and second, it lists the circumstances of the accident or violence that produced the fatal injury. In addition to the underlying cause of death, this section of the certificate provides for reporting the entire sequence of events leading to death as well as other conditions, known as comorbidities, which significantly contributed to death.[10]

Pennsylvania law requires that death reports be completed within four business days of death. Amendments may occur after an original death report is filed and accepted.

[9] CDC, Physicians' Handbook on Medical Certification of Death, 2003.
[10] Ibid.

Death Reporting Responsibilities

In the previous section we provided a high-level overview of the Pennsylvania death certificate/record/report and the data points collected therein. Properly completing a death record requires coordination from numerous parties and agencies. Listed below is a brief description of these parties involved in death report completion and the agencies that accept and track death record data.

Death Report Completion

Funeral Directors. In Pennsylvania, funeral directors are licensed by the Pennsylvania Department of State through the State Board of Funeral Directors. Funeral directors are employed by funeral homes, which are also inspected by the State Board of Funeral Directors to ensure the business meets the standards necessary to protect the public's interest and the standards of the profession. Funeral directors and funeral home staff are responsible for reporting accurate and complete death reports. They typically capture all the demographic information necessary to ensure the death report is completed accurately and timely, but also work with medical certifiers to ensure that the medical portion of the death report is completed. Beyond death reporting responsibilities, funeral director duties include, but are not limited to, the following:

- Transporting the deceased.
- Arranging funerals, visitations, and final dispositions.
- Coordinating out-of-state burials.
- Preparing contracts for prearranged services.
- Working with veterans' service organizations to properly handle a veteran's remains.

Medical Certifiers. In most cases, the physician who last treated the patient is responsible for certifying the death. Under the Vital Statistics Law, a medical certifier is one of the following:

- Physician.
- Certified Registered Nurse Practitioner.
- Physician Assistant.
- Dentist.
- Coroner/Medical Examiner.

Pennsylvania's VSL provides special requirements for the above. For example, a dentist may sign a death report only "if the dentist is a staff member of an approved hospital who attended the deceased during the

last illness, provided the death occurs in the hospital and the deceased had been admitted on the dental service," and in the case of a fetal death, "by the attending physician, certified registered nurse practitioner or physician assistant."[11] Additionally, if the deceased is a member of the physician's family or that of another medical certifier, then the medical certification shall be referred to another authorized medical certifier, or if none is available or willing to sign the death certificate, the coroner.

Coroners. Although listed as an eligible medical certifier under the VSL, coroners have a unique role and responsibility in the death reporting process. In Pennsylvania, most coroners are elected county positions with the responsibility for investigating deaths where "death is sudden or violent or is of a suspicious nature and character, to cause a careful investigation of the facts concerning said death to be made, to ascertain whether the death was due to other than natural causes."[12] Coroners need not be medical personnel; however, they must complete a minimum course of instruction of 32 hours covering crime scene investigation, toxicology, and forensic autopsies. Pennsylvania's County Code, at 16 P.S. §9521, provides "It shall be the duty of the coroner or the deputy coroner of any county in this Commonwealth, in all cases where death is sudden or violent or is of a suspicious nature and character, to cause a careful investigation of the facts concerning said death to be made, to ascertain whether the death was due to other than natural causes, and to make or cause to be made such an autopsy as the facts of the case may demand." The County Code, 16 P.S. §1218-B, states coroners are to focus on deaths such as:

1. Sudden deaths not caused by readily recognizable disease, or wherein the cause of death cannot be properly certified by a physician based on prior (recent) medical attendance.
2. Deaths occurring under suspicious circumstances, including those where alcohol, drugs or other toxic substances may have had a direct bearing on the outcome.
3. Deaths occurring because of violence or trauma, whether apparently homicidal, suicidal or accidental (including, but not limited to, those due to mechanical, thermal, chemical, electrical or radiational injury, drowning, cave-ins and subsidences).
4. Any death in which trauma, chemical injury, drug overdose or reaction to drugs or medication or medical treatment was a primary or secondary, direct or indirect, contributory, aggravating or precipitating cause of death.

[11] *See* VSL, Article V, Section 502 (2).
[12] *See* 16 Pa. Stat. Ann. § 9521.

5. Operative and peri-operative deaths in which the death is not readily explainable based on prior disease.
6. Any death wherein the body is unidentified or unclaimed.
7. Deaths known or suspected as due to contagious disease and constituting a public hazard.
8. Deaths occurring in prison or a penal institution or while in the custody of the police.
9. Deaths of persons whose bodies are to be cremated, buried at sea or otherwise disposed of so as to be thereafter unavailable for examination.
10. Sudden infant death syndrome.
11. Stillbirths.

To be clear, coroners are not medical examiners or forensic pathologists, which are another type of authorized medical certifier. In Pennsylvania, coroner backgrounds have included, physicians, nurses, police officers, paramedics, and most often, funeral directors.

Medical Examiners. Although most counties in Pennsylvania rely on elected coroners, some counties (Allegheny, Delaware, and Philadelphia) have replaced the position with medical examiners. Medical examiners differ from coroners in that a medical examiner has a medical school education and is board-certified in a medical specialty (e.g., forensic pathology). Medical examiners will oftentimes conduct the autopsies ordered by county coroners and be expert witnesses in legal proceedings.

Death Certificate Reporting Agencies

Once a death report is complete and is signed by the funeral director and the medical certifier, several additional agencies are involved in officially registering the death.

Local Registrars. Pennsylvania uses a system of local death registrars to collect and register paper-reported death reports on behalf of DOH. Local registrars are appointed by DOH to work with funeral directors to register deaths that occur in Pennsylvania for the first 90-days after the report of death is filed. Local registrars are responsible for issuing death certificates for the first 90-days after a death report is filed. There are approximately 170 registration districts in the state. A registration district is typically comprised of several municipalities in a geographic area. The number of registration districts per county is based on the population, typical number of death events reported annually, and

the geographic footprint. The local registrar must reside in the registration district that he/she serves. Prior to registering a death report, the local registrar is responsible for reviewing the death report provided by a funeral director or person acting as such to verify that the report is complete and accurate. The local registrar is also responsible for issuing disposition permits for each death registered. DOH pays registrars $1 for every death registered, and $3 for each death certificate issued, with a maximum allowable compensation of $85,000 per year.

Department of Health/Bureau of Health Statistics and Registries. The death registration workflow established by DOH is crucial to the overall process and ensures important quality control points from beginning to end. Once the death report has been completed, it is processed and registered at the state level by DOH's Bureau of Health Statistics and Registries (BHSR). This office is responsible for managing death records and logging COVID-19 deaths into the state dashboard. There are various post registration quality control measures including correspondence, ICD-10 coding (established by CDC), case surveillance through NEDSS (National Electronic Death Surveillance System) and amendment requests. The BHSR has been the official custodian of vital record keeping since the Department of Health's founding in 1906, and it is responsible for managing the data quality of its records. Beyond COVID-19, the department publishes annual reports known as the Vital Statistics Annual Report, which lists general trends for the Commonwealth and individual counties. In addition to the annual reports, the bureau utilizes a publicly accessible database known as EDDIE (Enterprise Data Dissemination Informatics Exchange). This system was created to publicly share aggregate data on death data for personal and public health research purposes.

National Center for Health Statistics. At the federal level, the National Center of Health Statistics (NCHS) collects data from state Vital Statistics offices (e.g., the Pennsylvania Department of Health). The NCHS is a subagency of the Centers for Disease Control and Prevention (CDC), which operates under the purview of the United States Department of Health and Human Services. NCHS was established in 1960 when the agencies of the National Office of Vital Statistics merged with the National Health Survey. NCHS has formally been part of the CDC since 1987. Today, the NCHS employs approximately 750 people and is headquartered in Hyattsville, Maryland. The intergovernmental coordination and data sharing between state health departments and the NCHS allows for the creation and existence of the National Vital Statistics System (NVSS). The NVSS provides the necessary information by which public health progress is measured in the United States. The data collected by this system helps law makers and public health experts advance

the interests of public health in America. NVSS data allows for more efficient deployment of federal resources to deal with public health threats. The NVSS in recent times has been fundamental in improving public health metrics such as infant mortality rates and average life expectancy. It also plays a critical role in combatting new and emerging public health threats such as the AIDS epidemic in the late 20th century and the ongoing COVID-19 pandemic.

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SECTION III – DEATH REPORTING

Fast Facts…

- *In March 2020, DOH required all COVID-19 deaths to be reported electronically through EDRS. Prior to this time, although EDRS was in existence, usage was not mandated. Many involved in death reporting were accustomed to a paper-based process. EDRS has improved timely reporting, something which has been an issue in prior years.*
- *There is a considerable amount of data about COVID-19 deaths on DOH's website. However, these data points are not well described--and some are contrary to other reporting sources—leaving users confused and suspicious. Better clarity about data sources is needed.*
- *"Cause of death" reporting is a complex process, but it serves as the basis for counting COVID-19 deaths. DOH follows guidance from the CDC, but DOH's counts are provisional; thus, final counts may change.*

Overview

Section II of this report outlined the process by which deaths are reported and the significant roles and responsibilities involved in that process. Within this section, we expand on these concepts and discuss five key contextual issues that are important in understanding death reporting, and specifically COVID-19 death reporting.

First, was the roll out of Pennsylvania's Electronic Death Registration System (EDRS). This online tool is used to electronically record deaths occurring in Pennsylvania. This system works on the "front-end" of the state's vital record system and allows users to report deaths more quickly and accurately. EDRS is available 24/7 to authorized users, e.g., funeral home directors and medical certifiers. While EDRS offers many improvements in the death reporting process, Pennsylvania did not mandate its usage until March 2020, as a result of the COVID pandemic. Early in the COVID-19 pandemic DOH mandated that all suspected or confirmed deaths from COVID-19 be reported through EDRS.

Second, was the fact that the timeliness by which deaths are reported and registered in Pennsylvania is not always as speedy as one might expect. For example, obtaining required signatures, or obtaining necessary demographic information from next of kin may impact the ability to report a death within the statutory requirement of four (4) business days after the date of death. Further, there is a distinction between reporting a death and registering a death. *Reporting* a death generally means that the death has occurred, and a funeral director or certifier has started the data collection process, whether it be through EDRS or a paper-based process. Conversely, *registering* a death means that the death report is complete, signed by all parties, and has been accepted by the Department of Health (DOH), Bureau of Health Statistics and Registries. Once a death is registered, DOH keeps the official death record on file in perpetuity. DOH *only reports data on registered COVID-19 deaths*, which are then sent to the Centers for Disease Control and Prevention and its affiliate the National Center for Health Statistics (CDC/NCHS), where final medical coding is completed. Further, while DOH reports registered COVID-19 deaths daily, these figures are still considered to be provisional; thus, the numbers are subject to change based on amendments to the original death record. Another problem presents itself in that there are multiple federal, state, and local entities that report COVID-19 deaths; however, not all these sources are providing uniform and consistent reports. For example, DOH's website presents an abundant amount of data

on long-term care facilities (i.e., skilled nursing facilities, assisted living, and personal care homes) but most of this data is self-reported, minimally verified for completeness, and obtained from sources other than death certificates. In the end, users are left with a baffling amount of data, but no linkage to its meaning or source, which leaves many end users questioning the accuracy of the information presented.

Third, within this section we decode the meaning of "cause of death" (COD) statements on a death report and how this information is used to identify deaths from COVID-19. COD as reported on a death report consists of two parts. Part I focuses on the chain of events causing death. This chain of events consists of three events: (1) the immediate cause of death; (2) the intermediate cause of death; and (3) the underlying cause of death. Part II focuses on the significant health conditions, also known as comorbidities, that contributed to the death, but are not included in the sequence of events listed in Part I. COD is determined by a medical certifier based on their medical training and judgment, but it is <u>not</u> a definitive conclusion about the death. Rather, it is a reasonable conclusion about the sequence of death based on medical opinion, and opinions about COD may differ.

We found that in Pennsylvania (as in many states) COD reporting is often incomplete or is unsuitable for medical coding purposes. Research from the CDC/NCHS revealed that in 2018, across all states, 34.7 percent of all death records had an "unsuitable" COD. In Pennsylvania, the unsuitability of COD statements was 39.9 percent, worse than the national average. It is important to underscore that an illogical or non-conforming COD sequence does NOT mean the death report is wrong, rather it means that sequence of death did not follow an appropriate sequence for medical coding purposes.

Fourth, with respect to COVID-19 deaths, COD statements are used as the basis for reporting death counts from the disease. Each state may use a slightly different process for counting a COVID-19 death, which can raise questions about whether a decedent died *from* COVID-19 or *with* COVID-19 and how to count the deaths. DOH uses criteria established by the CDC/NCHS and counts a COVID-19 death as one where COVID-19 is listed anywhere on Part I or Part II of the death report. DOH guidance issued to medical certifiers states that if COVID-19 did not directly cause or contribute to a death, it should not be reported on the death report. As a result, COVID-19 should only be reported if it was a cause or contributing factor in the death. DOH counts deaths where COVID-19 has been confirmed by laboratory testing, or where COVID-19 is presumed to be a cause based on clinical factors. Once DOH identifies a possible COVID-19 death, it is labeled with an internal classification as either: (1) COVID-19 Pending Test Results; (2) COVID-19; (3) COVID-19 Probable; or (4) COVID-19 Probable – Incorrect Terminology. Deaths labeled as "COVID-19 Pending Test Results" are <u>not</u> counted as a COVID-19 death

until the death record is appropriately amended by the medical certifier listed on the death record. This factor may explain why the reported number of COVID-19 deaths fluctuates between reporting periods.

Finally, we also reviewed a concept known as "excess deaths." This calculation compares the number of deaths that are expected to the actual registered deaths for a period. Reviewing all deaths in this manner provides additional perspective about mortality from the pandemic, as well as providing context about indirect deaths. We obtained expected death data from the CDC/NCHS and compared it to the registered (provisional) deaths that occurred in calendar year 2020. In 2020, Pennsylvania had 22,725 excess deaths, or approximately 17 percent more than what would be experienced in a "normal" year. We caution that not all these excess deaths may be directly attributable to COVID-19.

Issue Areas

A. Electronic Death Registration System Rollout

Pennsylvania lagged most other states in the adoption of an Electronic Death Registration System (EDRS), which is a system used to streamline death reporting/registering from an inefficient paper-based system to an electronic system. According to DOH's website:

> EDRS is a web-based application that simplifies the data reporting process while increasing data quality and supports the rapid-reporting of deaths that occur in Pennsylvania. EDRS is available to funeral directors and medical certifiers, including coroners, medical examiners, and medical professionals who are responsible for reporting deaths. EDRS is designed so that support staff may complete most of the data entry into EDRS. The funeral director or medical certifier can then review the case before submitting their certification of the death report.[13]

Pennsylvania's Adoption of EDRS

According to the CDC, the implementation of an EDRS offers a tremendous advantage, as it provides real-time edits and crosschecks of the data entered, which increases the quality of reporting, especially when

[13] *See* https://www.health.pa.gov/topics/Reporting-Registries/EDRS/Pages/EDRS.aspx, accessed February 22, 2021.

using web-based systems. An EDRS can facilitate quick hand-offs between reporters (e.g., split reporting by medical examiners and funeral home directors) and provides automated prompts (e.g., e-mail notifications) and workflow reminders.[14]

According to the CDC's guidance on EDRS, a larger jurisdiction, like Pennsylvania, should plan "about 2-3 years for full implementation." While the goal of an EDRS is more timely and accurate reporting/registering of death records, this objective can only be accomplished if EDRS is fully developed, and its use is mandated. Pennsylvania's system is continuing to evolve, although the mandate for its use was hastened as a result of the pandemic.

Pennsylvania's EDRS system is based on VitalChek. According to the Director for the Bureau of Health Statistics and Registries, EDRS was fully functional in April of 2016. Since that time, DOH continues to offer substantial training opportunities for end-users of the system. Additionally, the Director noted that DOH has made significant improvements to the system, including but not limited to, an EDRS bridge, which will allow coroners/MEs and funeral homes to interface with their case management software. As stated by the Director, "Pennsylvania is one of the few states that offer any type of interface let alone a bio-directional [sic] interface such as the EDRS bridge." DOH anticipates that about half of all coroner/ME offices will be using the EDRS bridge by the end of 2021. As shown in Exhibit 2, since FY 2009-10, nearly $6.3 million has been spent on EDRS and other shared systems.

[14] CDC, *Electronic Death Reporting System Online Reference Manual*, December 2016.

Exhibit 2

EDRS Expenses by Year*/

Fiscal Year	Total Expenditures
2009-10	$799,745
2010-11	137,755
2011-12	185,755
2012-13	164,786
2013-14	885,523
2014-15	416,672
2015-16	495,875
2016-17	955,726
2017-18	938,205
2018-19	764,495
2019-20	513,357
Total:	**$6,257,894**

Note: */Includes expenses which may be shared with other vital record systems used by the Department, including birth registry.
Source: Pennsylvania Department of Health.

There are four primary user groups within EDRS: medical professionals (certifiers), funeral directors, coroners/medical examiners, and local registrars. Exhibit 3 highlights these groups and the number of users in each group. As shown in Exhibit 3, with more than 45,000 users, medical professionals are the largest stakeholder group using EDRS.

Exhibit 3

EDRS Users by Stakeholder Group

Stakeholder	Volume of Users
Medical Professionals	45,010
Funeral Directors	5,543
Coroners/Medical Examiners	366
Local Registrars	340
Total:	51,259

Source: Pennsylvania Department of Health.

EDRS Use in 2020

EDRS use increased during the first quarter of 2020, when DOH mandated that all COVID-19 deaths were required to be reported electronically using EDRS. Through a series of State Registrar Notices, issued on March 6, 2020 (revised April 6, 2020), to each of the four primary EDRS user groups, DOH mandated the use of EDRS to ensure more timely reporting of deaths. In practice, exceptions were permitted for certain users where access to the internet or other connectivity problems were encountered. Additionally, because the death certificate process involves coordination between multiple reporting parties, a hybrid approach is also used that allows electronic and paper-based data submission.

The impact of DOH's decision to require EDRS for all COVID-19 deaths was apparent in the monthly totals reported to DOH. As shown in Exhibit 4, we obtained the total number of death records submitted to DOH by reporting type (electronic, hybrid, paper).

Exhibit 4

Monthly Death Reports Submitted to DOH By Reporting Method (Calendar Year 2020)

Month	Electronic (EDRS)	Hybrid	Paper-Only
January	1,945	6,856	3,721
February	1,694	6,352	3,413
March	2,210	7,817	2,098
April	5,244	9,797	388
May	4,776	8,777	298
June	3,353	7,582	278
July	3,281	7,981	275
August	3,269	7,954	273
September	3,260	7,822	255
October	3,481	8,317	268
November	4,673	9,223	284
December	7,303	11,510	365
Total	**44,489**	**99,988**	**11,916**

DOH mandates EDRS use for reporting COVID-19 deaths.

Source: Developed by LBFC staff from information provided by DOH.

As shown above, an immediate decrease in paper-based death reports is apparent from February 2020 (prior to DOH's mandate) and April 2020 (first full month after the mandate). In February, 3,413 reports were submitted via paper. Yet, in April that number dropped precipitously by 88.6 percent to just 388 records. Correspondingly, in February 2020, 1,694 records were submitted electronically by EDRS, yet by April 2020, 5,244

deaths were reported electronically, or an increase of 209.6 percent. As we will discuss later, not all these deaths are attributable to COVID-19, but the change from paper to greater use of electronic reporting was clearly influenced by DOH's mandate.

The medical providers who responded to our request for information noted that their organizations were using EDRS prior to the pandemic. One provider indicated that EDRS support and training was helpful and efficient, and further that as more funeral directors came online to EDRS, the process became easier for both the provider and the directors. A second provider, however, indicated that they do not find EDRS to be as "user friendly" as another system that this provider used prior to EDRS. This provider uses EDRS for 75 percent of its death reports, with the remainder being paper-based.

It is important to note that a significant number of deaths are still reported using a hybrid approach (99,988 in 2020). Ideally, all deaths would be reported electronically as it would greatly speed the timeliness and accuracy of the death record. As we will discuss in the next issue area, these are areas where Pennsylvania has struggled in prior years.

B. Data Discrepancies in Death Reporting

EDRS is a data collection tool. As mentioned, under the Vital Statistics Law, DOH is the official custodian of all death records in Pennsylvania, and EDRS serves as the primary mechanism for reporting those deaths to DOH. Consequently, because all deaths must be reported to DOH, using data from death records is likely to yield the best available analysis on COVID-19 deaths in Pennsylvania. However, other entities may also report death data or use different mechanisms for reporting deaths, which can easily confuse end-users looking to understand how many deaths are caused/related to COVID-19. Listed below are a few examples of different data points.

CDC/National Center for Health Statistics

Each state collects and uploads death records to the National Vital Statistics System maintained by the CDC through the NCHS. Cases are classified using standardized codes developed by the World Health Organization and published in the International Statistical Classification of Diseases and Related Health Problems, or more commonly known as ICD-10. For COVID-19 cases, the WHO uses two specific ICD-10 codes:

- **U07.1.** This code is used for all confirmed COVID-19 cases. A confirmed case is one that has been confirmed by a laboratory test for COVID-19 and which is reported to the PA-NEDSS system, Pennsylvania's version of the National Electronic Disease Surveillance System.[15]

- **U07.2.** This code is used for all probable COVID-19 cases. Probable means that there is no confirmed laboratory test for the patient, or the results of the test may be pending. Probable cases would include meeting certain clinical criteria (e.g., the patient had at least two known COVID-19 symptoms, such as fever, cough, etc.) and epidemiological linkage (e.g., close contact with a confirmed case of COVID-19 or a member of a risk cohort).

CDC/NCHS uses incoming data from death records to produce *provisional* COVID-19 death counts. However, an important distinction needs to be drawn about these two codes. According to the CDC/NCHS, because certifiers in the United States do not typically report laboratory test results on death certificates, NCHS did not implement U07.2 for mortality statistics. When laboratory confirmation is inconclusive or unavailable, certifiers determine and report the causes of death on the death certificate based on medical history, medical records, autopsy report (if available), and other relevant sources of information.[16] Therefore, death data is only provisional and is continually being revised. To this point, guidance published on provisional deaths from the CDC/NCHS notes the following:[17]

- **Provisional counts are not final and are subject to change**. Counts from previous weeks are continually revised as more records are received and processed.

- **Provisional data are not yet complete**. Counts will not include all deaths that occurred during a given time period, especially for more recent periods. However, the completeness of the data can be estimated by examining the average number of deaths reported in previous years.

- **Death counts should not be compared across states**. Some states report deaths to NCHS daily,

[15] PA-NEDSS is Pennsylvania's Electronic Disease Reporting system. PA-NEDSS allows for the healthcare system to report diseases and investigative findings 24/7 to DOH. Consistent with our objectives, we anticipate that future reports will look more closely at COVID-19 testing and reporting.
[16] CDC/NCHS. Coding Deaths Due to COVID-19, *See* https://www.cdc.gov/nchs/covid19/faq.htm#Coding-DeathsDuetoCOVID19, accessed, March 23, 2021. The CDC/NCHS uses the term death certificate commonly here.
[17] CDC/NCHS, Understanding the Numbers: Provisional Death Counts and COVID-19, accessed at cdc.gov, March 16, 2021.

while other states report deaths weekly or monthly. State vital record reporting may also be affected or delayed by COVID-19 response activities.

As such, it can be confusing to access data from the CDC/NCHS and see numbers that appear lower than what is reported on Pennsylvania's COVID-19 dashboard. This occurrence may lead users to believe Pennsylvania's numbers are inflated, when in fact, as we will discuss in the next issue area, it is really a matter of timeliness in reporting.

County Coroners

As discussed in the background section, county coroners and medical examiners have an important role in reviewing and investigating deaths. Coroners are typically involved in reviewing/investigating deaths that occurred at home (if decedent was not under the care of a medical professional), in certain congregate facilities (e.g., prisons and jails), or from unnatural causes in their respective counties. However, DOH reports COVID-19 deaths by the decedent's residence. For example, if a decedent lived in one county and dies in a hospital or at a facility in another county, the death record will show the death occurring in the residing county.

In fact, coroners have sought a greater role in COVID-19 death reporting. Based on media reporting, the basis for this argument centered on the following:[18]

1) Under Pennsylvania law, coroners have a responsibility to investigate deaths "from contagious disease" of which COVID-19 is clearly a highly contagious disease.

2) They had a better sense of deaths occurring in their respective counties because they had better relationships with EMS, hospitals, and physicians.

As we now know, DOH saw the situation differently, in part, because while coroners had authority to investigate certain qualifying deaths there was no reporting mandate to coroners, unlike the reporting mandate to DOH for deaths and contagious disease-related case data. Thus, DOH, under authority of the VSL, pursued a centralized approach with it taking the lead in death reporting. DOH initially relied upon reconciling death reporting from PA-NEDSS and death certificates. However, many county coroners continued to vocally express frustration or outright disagreement with COVID-19 death data being reported by DOH. Several

[18] *See* Spotlight PA, "Pa Coroners, health department at odds over how to handle suspected coronavirus cases, potentially affecting death count," April 10, 2020.

media outlets reported on this data discrepancy between coroners and DOH, which likely added to confusion among end-users.[19]

Senate Bill 1164 of 2020 sought to clarify some of this confusion by requiring respective county coroners to be notified of all deaths from "any disease constituting a health disaster emergency or pandemic." The bill also would have allowed coroners to have access to DOH's databases, including specifically, death certificates. This bill passed the House and Senate on October 26, 2020, but it was vetoed by the Governor on November 3, 2020. In his veto message to the Senate, the Governor cited additional reporting mandates that may cause delays in reporting to DOH and the potential release of "highly sensitive personal information" protected by the Vital Statistics Law.

During our research for this study, we interviewed the president of the County Coroners' Association, who expressed to us frustration about DOH, EDRS, and the death reporting process. We also discussed the nuances of decedents dying *from* COVID-19 and dying *with* COVID-19 and how these distinctions could lead to differing aggregate death counts at the county and state level (see also discussion that follows later).

Long-Term Care Facilities

Another area of confusion concerning COVID-19 death reporting surrounds how long-term care facilities report data to DOH and how those totals are reported. This issue is significant because COVID-19 has proven to be especially lethal to the elderly, many of whom may reside in congregate care facilities. Moreover, Pennsylvania has many of these facilities within its borders.[20] Additionally, recent attention has turned to New York state and the admission from state officials there that data on deaths occurring in nursing home had been underreported. For these reasons, we looked closely at the publicly available data presented on DOH's website.

Before discussing deaths in long-term care facilities, it is important to understand the distinction and regulatory oversight of these facilities. The term "nursing home" is often used generically to mean any type of facility for the aged or infirmed, who require assistance with "activities of daily living" (e.g., dressing, bathing, medication management, etc.). However,

[19] *See* Pittsburgh Post-Gazette, "Dispute between state and coroners over COVID-19 death counts might have a resolution," May 25, 2020. Lancasteronline.com, "COVID-19 death counts between coroners and the state will likely never match. Here's why." December 2, 2020.

[20] According to the Kaiser Family Foundation, a nationally recognized leader in national health issues, Pennsylvania ranks sixth in the total number of certified nursing facilities.

there are differences between the level of care provided and the regulatory responsibility for these facilities. Exhibit 5 highlights these distinctions.

Exhibit 5

Long-Term Care Facilities*
Description and State Regulatory Oversight

Skilled Nursing Facility
Regulatory Agency ⟹ Department of Health

- 24/7 nursing care and regulations specify minimum nurse staffing levels.
- Settings are typically medically-based.
- Offer reabilitation services and advanced therapies.
- Generally more expensive than other types of in-facility care.
- Services may be covered by Medicare/Medicaid.
- Must meet state and federal regulations.

Assisted Living
Regulatory Agency ⟹ Department of Human Services

- Designed for residents who need less daily care than a SNF, but still require assistance with some tasks (e.g., laundry, medication).
- Residential setting.
- Must have kitchenettes and private bathrooms.
- Typically associated with a SNF, allowing residents to transition to SNF, if necessary.

Personal Care Home
Regulatory Agency ⟹ Department of Human Services

- Typically privately-owned.
- Provide similiar services as assisted living, but may be in a smaller facility.
- Varying ameneties offered by facilities.

Note: */ This is not a description of all congregate care living facilities, but these are the types most closely associated with the generic term "nursing home." Additional types of facilities can be found at https://www.human-services.state.pa.us/human_service_provider_directory.
Source: Developed by LBFC staff.

As highlighted in the previous exhibit, nursing homes are defined as skilled nursing facilities (SNFs). DOH has a two-pronged oversight role with these facilities. Through an agreement with the Centers for Medicare and Medicaid Services (CMS), DOH inspects SNFs (known as facility

surveys) and investigates complaints. DOH also has a licensing responsibility, which ensures SNFs are meeting certain state-mandated requirements (e.g., staffing levels, building requirements, etc.). The Department of Human Services (DHS) has a similar regulatory responsibility, but only with assisted living and personal care homes.

DOH-Presented Data about COVID-19 and LTCFs.

While the dual regulatory approach is confusing to many, perhaps even more confusing is accessing COVID-19 related data about these facilities. To access this information, one must use DOH's website, which is the entry point to most Pennsylvania COVID-19 data. For example, the state's COVID-19 dashboard is listed there, as well as links to various data sets where users can "get the latest information on COVID-19 in PA."[21] A link from this site labeled "Long-term Care Data" takes users to a page with a heading labeled "COVID-19 Long-term Care Facilities Data for Pennsylvania." From there, users have access to a confusing array of additional links, tables, and graphs as duplicated in Exhibit 6.

[21] *See* https://www.health.pa.gov/topics/disease/coronavirus/Pages/Cases.aspx. DOH's COVID-19 dashboard discloses the number of confirmed and probable cases, negative test results, deaths, ZIP-code level data, hospital preparedness, and case and death demographics. The data is updated by noon each day.

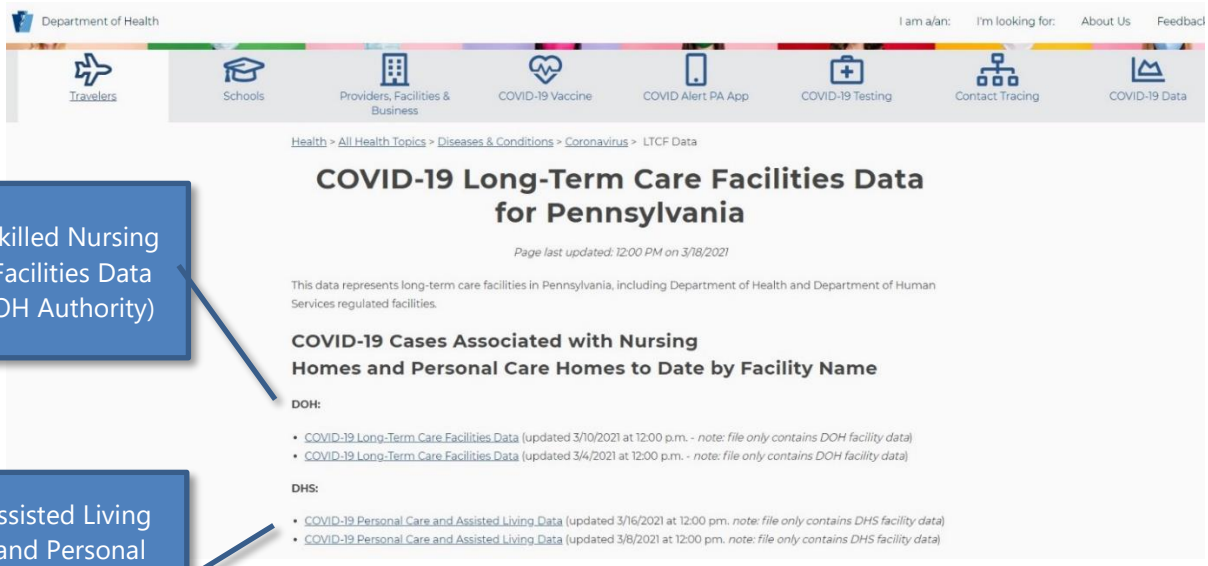
Exhibit 6

Finding LTCF COVID-19 Death Data from DOH's Website

1. Skilled Nursing Facilities Data (DOH Authority)

2. Assisted Living and Personal Care Homes Data (DHS Authority)

3. Summary Table of Cases and Deaths by County (i.e., facility totals)



COVID-19 Cases Associated with Nursing Homes and Personal Care Homes to Date by Facility County

Facility County	Number of Facilities with Cases	Number of Cases Among Residents	Number of Cases Among Employees	Number of Deaths
ADAMS	12	440	87	62
ALLEGHENY	161	5497	2174	991
ARMSTRONG	10	380	47	44
BEAVER	17	1082	255	218
BEDFORD	5	284	33	43
BERKS	41	2203	422	405
BLAIR	23	1081	172	135
BRADFORD	8	317	78	33
BUCKS	74	3004	857	679
BUTLER	29	1504	209	272
CAMBRIA	29	1094	162	197
WASHINGTON	27	1075	129	139
WAYNE	5	89	20	21
WESTMORELAND	51	2089	321	288
WYOMING	3	106	28	23
YORK	40	1980	288	310
PENNSYLVANIA	1561	68716	13951	12821

All 67 counties are listed

How many deaths in LTCFs?

Listed as **12,821**, as of March 18, 2021.

Source: Developed by LBFC staff from review of DOH websites, accessed March 18, 2021. Images are actual screen shots from that day. Images were taken in a series of screen captures; thus, images appear to be different sizes.

As shown above, there are three primary data points available to end-users about COVID-19 in Pennsylvania's LTCFs. First, are the two most recent weeks of data about SNFs in Pennsylvania. Links here lead users to a spreadsheet, which when opened lists each SNF and the following additional information:

- Facility identification number,
- City,
- County,
- All beds,
- Current census,
- Resident cases to display,
- Resident deaths to display, and
- Staff cases to display.

Second, as shown in Exhibit 6, users can also select a link for information on "COVID-19 Personal Care and Assisted Living Data," with two of the most current weeks of data available. When clicking on these links, another spreadsheet opens, which lists facilities and the following additional information:

- Type of service,
- County,
- License number,
- Facility name,
- COVID-19 positive residents,
- COVID-19 resident deaths, and
- COVID-19 positive staff.

Finally, as shown by the third box on Exhibit 6, a summary table is presented with the title "COVID-19 Cases Associated with Nursing Homes and Personal Care Homes to Date by Facility Count." Columns on this table include the following:

- Facility county,
- Number of Facilities with cases,
- Number of cases among residents,
- Number of cases among employees, and
- Number of deaths.

Given the location of the summary table, it is easy to assume that the table is intended to summarize the data from the above spreadsheets, i.e., SNFs and personal care/assisted living centers. However, that is <u>not</u> the case.

We reviewed the table and sought to duplicate the number of LTCF deaths by county. For example, Adams County is listed as having 62

LTCF deaths. However, when we accessed the documentation, we found the number was much higher than 62. We found the deaths were as high as 73 in just SNFs and an additional 10 deaths were recorded in personal care homes/assisted living facilities—totaling 83 deaths. Further, because DOH/DHS does not list death counts fewer than five—only listing a range between 1-4—it is likely the death count is even higher, possibly as high as 94. Therefore, the reporting for this county alone may differ by more than 50 percent.[22]

Even more troubling though is that a significant number of facilities—both SNFs and personal care/assisted living facilities—show no data. For example, when we reviewed the two spreadsheets, we found 138 of the 693 SNFs were listed as "no data." Further, 432 of the 1,212 total personal care homes/assisted living facilities also had "no data." This equals nearly 20 percent of total SNFs and 35 percent of personal care/assisted living facilities. These are very high percentages of facilities that are not reporting information.

We inquired about these differences because it is a very confusing presentation when seeking data on COVID-19 deaths in LTCFs. DOH confirmed to us that the table (labeled as "3" in Exhibit 6) is <u>not</u> a summary of the two spreadsheets. Instead, this table represents summary data on facilities collected from PA-NEDSS. Specifically, DOH noted the following:

> The spreadsheets referenced as being linked above are facility-reported data. The table below is using data from the National Electronic Disease Surveillance System (NEDSS). The department has been collecting information on cases with long-term care facilities since the pandemic began last March. However, in NEDSS, cases are matched to addresses. Therefore, if a specific address houses a skilled nursing facility and a personal care home at that same address, we often do not know if the case (and death) occurred within the skilled nursing facility or the personal care home. That is why that chart of cases and deaths within a county combines facility types.

Consequently, on one data source (facility spreadsheets), data is self-reported via DOH-mandated online surveys; yet, for another data presentation, DOH extracts possibly conflicting information based on addresses. While we see value in presenting some means of corroborating evidence

[22] We attempted to reconcile other counties, but the data was too inconsistent to make comparative assessments. Further, the spreadsheets were not always consistently labeled leading us to question which version was correct. For example, a link for data on SNFs indicated that the file was updated on 3/26/21 at 9:00 a.m. However, we accessed the link on 4/1/21 and it pointed us to a spreadsheet with data from 3/23/21. This happened on more than one occasion, which could be due to a timing difference in when data is updated to DOH's website. Links for DHS data did not have this issue.

for facility reported data (e.g., NEDSS facility address information), without a clear distinction between these data sources, users are left confused. Worse yet, for individuals who are relying on this information to make decisions about family members in these facilities, they are left without a clear understanding of what the data represents.

Nonetheless this response still does not address the issue of why so many facilities are listed as "no data." We asked this specific question to the Department staff, who responded with the following:

> A facility may be listed as no data because they reported either no data, or inaccurate or incomplete data. We are working to assist facilities that are reporting inaccurately or incompletely, but the facilities are required to report all resident and staff cases since the pandemic began, as well as deaths. If a resident was to contract COVID-19 at the facility and later die, it should be counted as a death. Other reporting requirements, such as to the federal reporting system, look at seven-day case numbers, and that may be one reason for the confusion in reporting incomplete data.

We find it hard to believe that more than a year into this pandemic that facilities are still having a difficult time reporting accurate information to DOH. Nevertheless, if that is the case, there should be some effort to verify or reconcile the data. We asked DOH this question, and DOH noted further:

> Yes, if the number of deaths is higher than the number of cases, for example, the facilities [sic] numbers are flagged and marked as no data for being inaccurate.

Obviously, there are facilities that continue to have difficulty understanding this reporting requirement. Moreover, DOH's efforts to "assist facilities that are reporting inaccurately or incompletely," is not having the desired effect.

In summary, LTCF death data is so inconsistent and unreliable that it does not fulfill its purpose of accurately informing the public. We encourage DOH to seek stronger means to ensure facility reporting compliance or seek an alternative reporting mechanism that assures public users have access to this critical information. One alternative would be to also use decedent address information from death records. Further, the data should clearly indicate how it is collected, when it is collected, as well as provide an appropriate context for the data.

C. Death Reporting Workflow and Timeliness of Death Reporting

In the last issue area, we discussed how different sources and reporting agencies may have different death data. As indicated in those discussions, a key cause of these discrepancies is related to timing differences between when a death is reported and registered and when it is "officially" included in a death count. Stated differently, all deaths are counted, but when they are counted and by whom they are counted can vary.

Another confusing concept is the distinction between a death certificate and a death record. According to DOH, a death certificate is a product that is issued against the official copy of the death record. DOH uses specific terminology to describe various phases in this process. For example, in a linear depiction from reporting to creation of the record, a "certificate of death" reporting form is completed and signed. Once that form is processed and registered, a "death record" is created. "Death certificates" are then issued from the official version of the death record on file at time of issuance of the death certificate.

Timeliness of the Workflow Process

DOH is the custodian of all death records in Pennsylvania. Death data comes to DOH via death reports (required to be reported within four business days). DOH receives death reports electronically via EDRS and by paper (COVID-19 deaths are primarily via EDRS). Once received by DOH, the report is checked and verified, where it then becomes a registered death record.

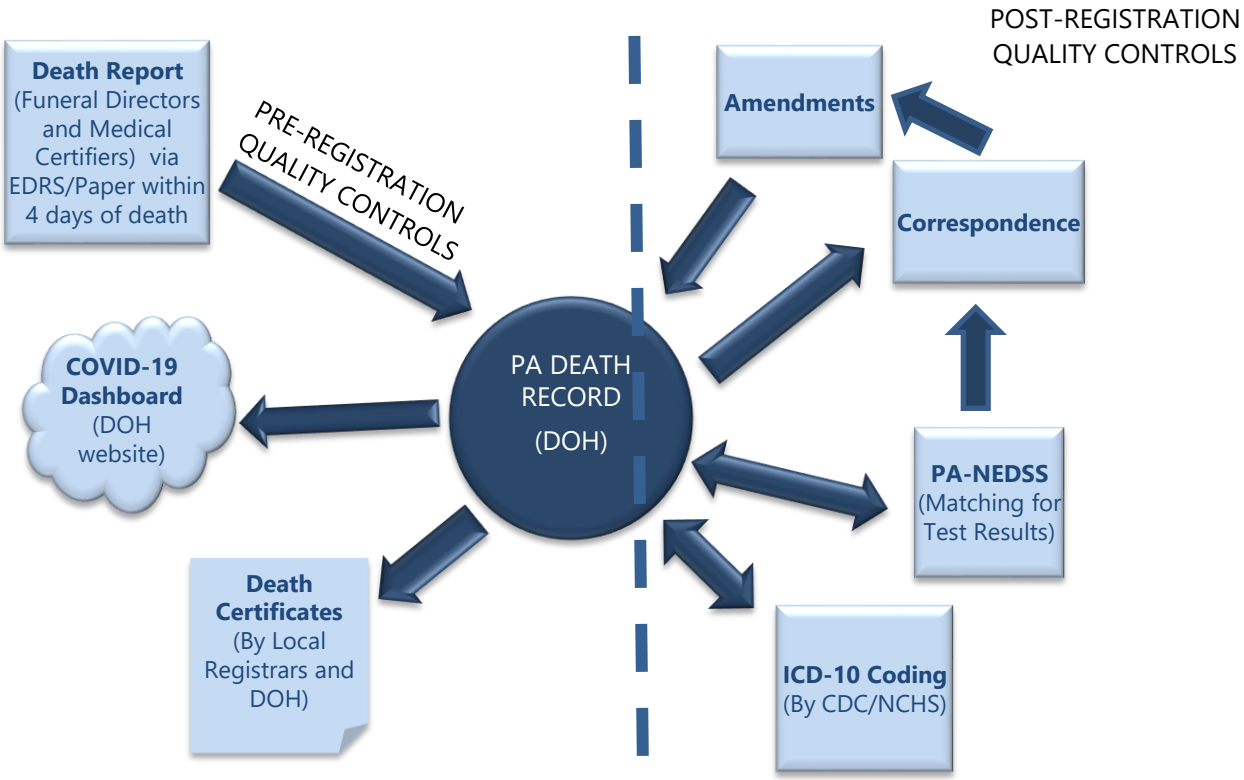
Additional post-registration review may still occur, which could alter the record. For example, the record will be checked against PA-NEDSS for any COVID-19 test results. Further, if there are pending test results that were unknown at the time of death reporting, those results may require an additional change to the record, which occurs through a correspondence/amendment process.[23] In cases where DOH is seeking clarification about test results, DOH will send a letter to the medical certifier asking them to update the record with new information. DOH informed us that they will send an initial notice requesting an update, a second notice, and then a final notice. If necessary, staff will also place telephone calls to

[23] Note: The decedent's next of kin may not be aware of these changes to the death record. For example, if a death certificate is issued at the time of the funeral, but the cause of death is later amended by the medical certifier, only future issued copies of the death certificate would reflect this update. DOH informed us that only if the next of kin requested the amendment, would they be informed of the change. DOH stated that this process is standard for all states, not just Pennsylvania.

request an amendment. DOH stated that there is no prescribed timeframe by which these notices are sent but is instead driven by case-load in registering new deaths and resources available to follow-up on the notifications. As a result, the amendment process can heavily influence the timeliness of the workflow process. Additionally, as described in the previous issue area, the CDC will receive the death record and apply ICD-10 coding (e.g., U07.1 for COVID-19 deaths). Exhibit 7 outlines the general death workflow process for COVID-19 deaths.

Exhibit 7

COVID-19 Death Record Workflow



Source: Developed by LBFC staff from information provided by DOH.

The above exhibit demonstrates the numerous steps that occur within the death record workflow process, and how those steps may impact timeliness. Consequently, although DOH provides a daily report of deaths from COVID-19, that number should not be taken to mean that the deaths occurred within the last 24 hours. In fact, given the workflow processes involved, daily reported deaths likely occurred a few days earlier and in some isolated cases, may have occurred weeks ago. This is especially relevant when comparing data from different reporting sources, e.g., coroners, long-term care facilities, hospitals, etc., which

might be reporting actual deaths in a real-time environment, unlike DOH's reporting process (see also Issue Area E).

Timeliness in Reporting to CDC/NCHS

As shown in Exhibit 7, DOH transmits its death records to the CDC/NCHS, where the data is reviewed, and appropriate ICD-10 codes are applied to the records. Since 1967, the CDC/NCHS has been using its "Mortality Medical Data System," to automate the entry, classification, and retrieval of cause-of-death information reported on death certificates. While most deaths are done electronically using four programs that will convert text to specific medical codes, representatives from the CDC/NCHS told us that COVID-19 deaths are manually coded.[24] For this reason, timely submission of death data to the CDC/NCHS, while critical for all deaths, is especially critical for COVID-19 related deaths because it takes more time to properly code the death record.

Pennsylvania has, at least until recently, had a lackluster history in transmitting records to the CDC/NCHS in a timely manner. In fact, until last year, Pennsylvania was consistently one of the slowest reporting states. Undoubtedly, this was due to the slow roll-out of EDRS and Pennsylvania's continued reliance on paper-based records.

The CDC/NCHS monitors timeliness for each of the states and calculates an "Average Calculated Lag" in days. Researchers calculate the lag based on the previous year's data and present a percentage of records received for a specified end date. For example, the 2020 report will include lag calculations based on 2019 deaths and a percentage of records received through December 15, 2020.

As depicted in Exhibit 8 below, Pennsylvania often significantly exceeded the median calculated lag for all states. However, more recently, Pennsylvania has fallen within the median average for all states.

[24] The four programs used by the CDC/NCHS are the Mortality Medical Indexing, Classification, and Retrieval (MICAR); Automated Classification of Medical Entities (ACME); TRANSlation of Axis (TRANSAX); and Super-MICAR Data Entry (Super MICAR). These are complex programs that work in connection with each other. For example, SuperMICAR allows data entry personnel to type in exactly what appears on the death certificate. It then processes the data, dividing terms, replacing words with synonyms, dropping unnecessary words, and arranging words in proper order to be found in NCHS' MICAR dictionary. The result is a file that can be processed through MICAR software to produce ACME input files. *See* https://www.cdc.gov/nchs/nvss/mmds/about_mmds.htm.

Exhibit 8

Average Calculated Lag Days in Death Reporting to the CDC/NCHS*

Year	Pennsylvania	Median Average for All States**
2015	132	9
2016	70	7
2017	96	6
2018	19	4
2019	13	4
2020	2	2

Note: */Lag is calculated for each death record based on the registration date when a valid date is available; otherwise, the calculated lag for the record is based on the event date.
**/New York City and the District of Columbia are reported separately and are included in this calculation.
Source: Developed by LBFC staff from information obtained from CDC/NCHS through DOH.

Significant improvements have been made since 2015 when the lag was reported at 132 days and was the worst in the nation. However, it will remain to be seen how well Pennsylvania does with the impact from COVID-19 on overall operations, as well as the influx on new cases being reported. We asked the CDC/NCHS' Chief of the Mortality Statistics Branch about his perceptions of Pennsylvania's reporting to CDC/NCHS. As of January 2021, he noted that in the early days of the pandemic there was a "lag" in reporting, which he attributed to staff transferring to new remote working protocols. He further checked with the data acquisition staff, and reported the following to us:

> …paper records from Pennsylvania are still a bit "laggy", but not substantially so. So, yes, I can confirm that we are not currently seeing any major irregularities or errors, and we don't currently have any significant concerns about the PA vital records data.

Why timely reporting to the CDC/NCHS matters. We were encouraged to hear of the Chief's perceptions of Pennsylvania's vital records data, and it is encouraging that the CDC/NCHS is receiving timelier data than in the past years. This aspect is a significant point because as depicted in the COVID-19 death workflow process in the previous Exhibit 7 there is an interplay between the CDC/NCHS in determining the final death description.

All states transmit death data to the CDC/NCHS, which includes the who, what, when, where, and why surrounding that death. The "why" is arguably one of the most significant aspects for public health purposes because it allows for an accurate and consistent count by death classification. At the CDC/NCHS, impartial and highly trained "nosologists" review death causes and assign standard codes to describe the sequence of how a person died.[25] These codes, which are derived from medical certifiers' opinions from the cause of death statements on a death record, are essentially the final cause of death description for analytical purposes.

The state of Oregon (which has the same death workflow as Pennsylvania) describes this interplay between the states and CDC/NCHS as follows:

> After a death record has been certified, the cause of death section is forwarded to CDC's NCHS. NCHS nosologists review the data, determine its accuracy, electronically and manually code the deaths using ICD-10 classification, and report back the final and coded cause of death to the states. This process has been in place since the 1980s for all causes of death.

The benefit of reporting deaths that moved though the NCHS process is that these data represent the most accurate death counts. For example, the "why" surrounding the deaths have undergone review, and if the CDC/NCHS determines the death is a COVID-19 death, it has been coded using the standard ICD-10 code (U071) and DOH would have been notified.

However, as we showed previously, a death can take several days (at best) from the date of death to be registered. This is even before the CDC/NCHS's review. Moreover, according to CDC/NCHS statistics, 80 percent of deaths are electronically processed and coded by NCHS nosologists within minutes; yet, COVID-19 deaths must be coded manually, which takes an average of seven days.[26] The fact that this CDC/NCHS coding process takes so long is evidence to the thoroughness by which the nosologists are reviewing these deaths. Obviously, the disadvantage is a delay of one to three weeks for data review and return to DOH. The data lag means CDC/NCHS provisional death counts may not reflect all deaths reported by the state during a given time period, especially for more recent periods—but as these periods increase—the accuracy of the death data will improve.

In summary, while a death record contains the who, what, where, when, and why surrounding the death—it is just the starting process for a more

[25] Nosology is branch of medicine that deals with the description of diseases. Nosology allows statisticians and other researchers to use the data for disease prevention and other public health purposes.
[26] *See* https://www.cdc.gov/nchs/nvss/vsrr/COVID19/index.htm

detailed review that occurs over time and by independent experts that classify disease at the federal level. To this point, the timeliness by which death reports reach DOH—and with accurate statements about the chain of events leading to death (i.e., "the why")— the greater confidence in our public health data can be achieved. Unfortunately, as we learned, uniform and accurate "cause of death" reporting has been notoriously poor, even before the COVID-19 pandemic.

D. Understanding Cause of Death Reporting

The federal government has worked with states to collect and standardize death reporting since the early 1900s. As discussed in the Background Section of this report, cause of death and a decedent's demographics are first reported on a "certificate of death" reporting form. For COVID-19 deaths, as mandated by a State Registrar notice in March 2020, this process must be completed through EDRS (although some paper death reports are still processed).

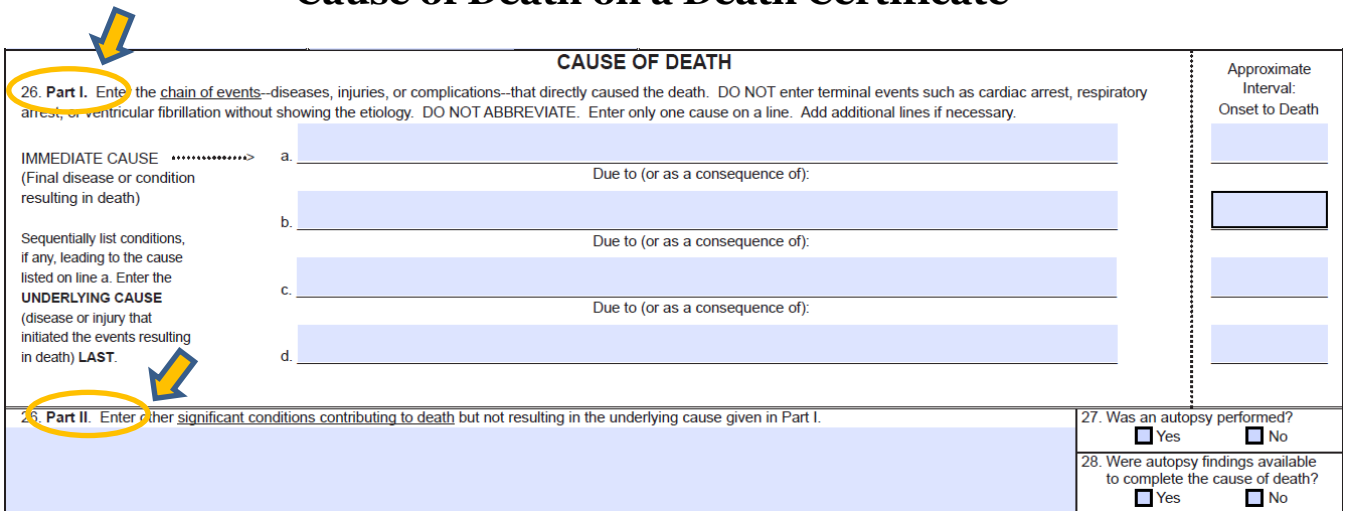
Cause of death is recorded in two parts on a death certificate. **Part I**, known as the chain of events (or sequence of death) captures the diseases or conditions resulting in death. **Part II** of the cause of death captures *comorbidities*, or health conditions that contribute to death, but are not the underlying cause of death. Part I and Part II (as well as some other health-related fields) are completed by medical certifiers (e.g., physicians), who also (but not always) pronounce and certify death. We will discuss each of the aspects in more detail because it is critical to understanding more about COVID-19 deaths.

Part I and Part II – Cause of Death

Exhibit 9 reproduces Part I and Part II from a blank Pennsylvania death certificate. These are standard fields found on most state death certificates.

Exhibit 9

Cause of Death on a Death Certificate



CAUSE OF DEATH

26. **Part I.** Enter the chain of events--diseases, injuries, or complications--that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.

Approximate Interval: Onset to Death

IMMEDIATE CAUSE (Final disease or condition resulting in death) ····> a.

Due to (or as a consequence of):

b.

Due to (or as a consequence of):

Sequentially list conditions, if any, leading to the cause listed on line a. Enter the **UNDERLYING CAUSE** (disease or injury that initiated the events resulting in death) **LAST**.

c.

Due to (or as a consequence of):

d.

26. **Part II.** Enter other significant conditions contributing to death but not resulting in the underlying cause given in Part I.

27. Was an autopsy performed? ☐ Yes ☐ No

28. Were autopsy findings available to complete the cause of death? ☐ Yes ☐ No

Source: Developed by LBFC staff. Reproduced from Pennsylvania form H105-143, Rev. 11/17.

Although the Exhibit above reproduces a paper certificate, on EDRS the fields would be essentially the same, only in an electronic format where medical certifiers can type the required information (see discussion that follows).

Looking closer at Part I—or the Cause of Death—the field is further divided by "Immediate Cause" and "Underlying Causes." The immediate cause is the proximate, or most recently developed final diagnostic condition causing death.[27] Note that the immediate cause of death is specifically not a mechanism of death (e.g., heart attack), but is instead the final condition causing death (e.g., hypoxemia). Finally, the underlying cause(s) is the foundational diagnosis or condition from which the remainder of the death sequence begins.[28] There is usually only one underlying cause of death, but there could be several intermediary causes of death conditions, which lead to one final immediate cause of death.

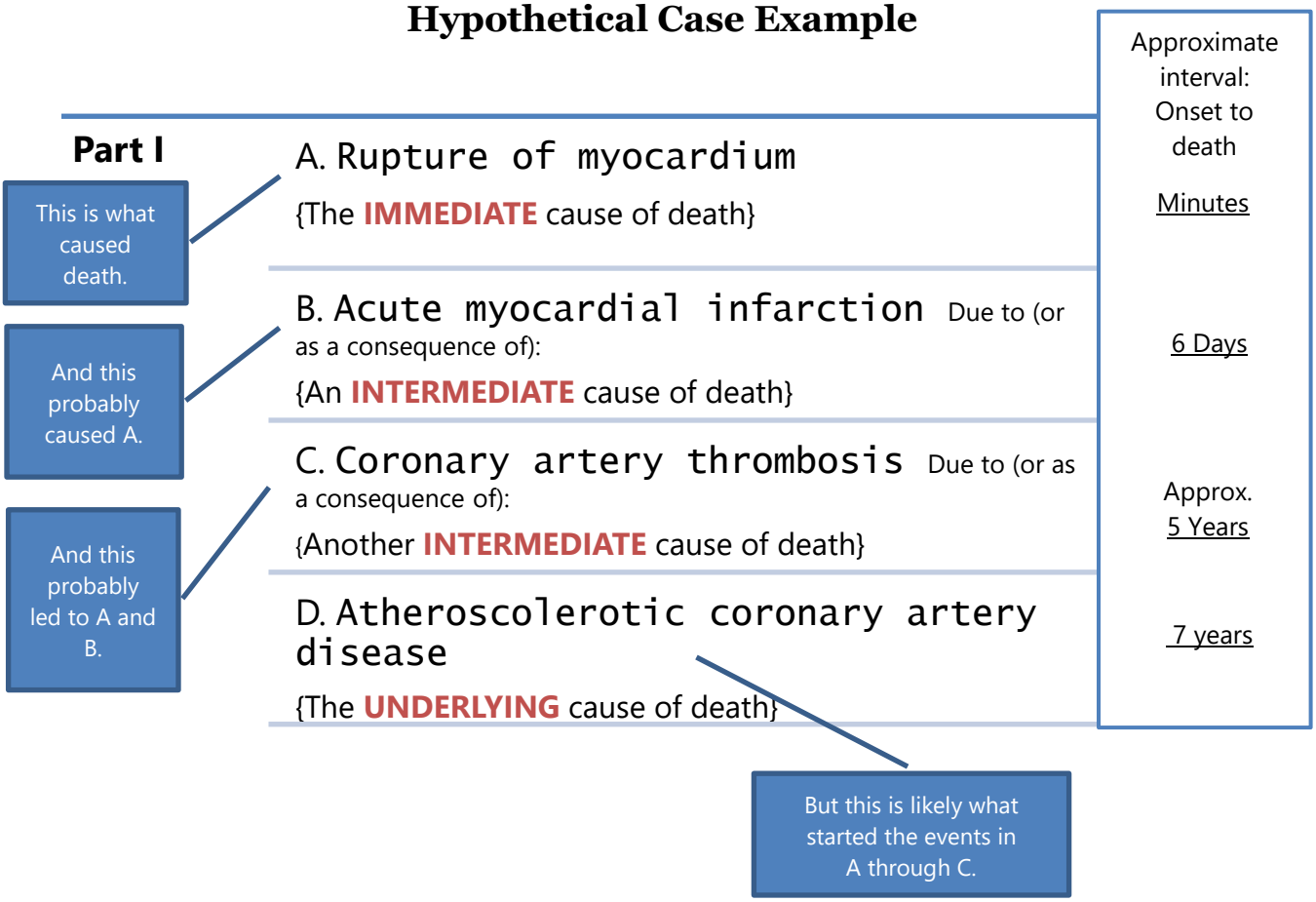
Looking to the right of the immediate, intermediate, and underlying causes are fields where a time sequence is also listed. In almost all cases, a time-linked chain of causation is also established, such that the immediate cause of death was a consequence of a somewhat longer-duration diagnosis, which in turn was a consequence of an even longer-duration diagnosis, and so on through as many or few intermediate causes as necessary until reaching the true underlying cause of death.[29]

[27] Swain, Georffrey. "Death Certificates: Let's Get it Right," American Family Physician, February 15, 2005.
[28] Ibid.
[29] Ibid.

Exhibit 10 highlights this sequence with a hypothetical case example.

Exhibit 10

Part I – Cause of Death Reporting
Hypothetical Case Example



Source: Developed by LBFC staff from information adapted from the College of American Pathologists, *Cause of Death and the Death Certificate*, 2006. Image is enlarged to better illustrate the chain of events.

As shown in the hypothetical case example, if we look at the cause of death sequence in reverse order a clearer picture emerges of how this person died. For example, the decedent had atherosclerotic coronary artery disease, a specific type of hardening of the arteries for seven years. At some points in the past five years, that hardening of the arteries led to a coronary artery thrombosis, essentially a blood clot which restricts blood flow to the heart. In turn, six days ago, this blood clot caused an acute myocardial infarction, more commonly known as a heart attack. According to the cause of death sequencing, this heart attack then led to the rupture of the myocardium, which led to areas of the heart rupturing from which the patient died.

Part II (Comorbidities). Up to this point, we have only discussed Part I of the death certificate, which again covers the sequence of death events (i.e., immediate, intermediate, underlying). Part II of the death certificate covers comorbidities, or the items that medical certifiers can enter on the death certificate that contribute or worsen the death sequence (Part I), but these diseases or conditions did not cause the death. To discuss the significance of comorbidities on a death certificate, refer to the hypothetical decedent in the previous exhibit and assume that Part II of her death certificate looked like the following (see Exhibit 11):

Exhibit 11

Part II – Cause of Death Reporting
Hypothetical Case Example

Part II. Enter other significant conditions contributing to death, but not resulting in the underlying cause given in Part I.

Diabetes, Chronic obstructive pulmonary disease (COPD), smoking

Source: Developed by LBFC staff from information adapted from the College of American Pathologists, *Cause of Death and the Death Certificate*, 2006. Image is enlarged to better illustrate conditions.

In this hypothetical example, the medical certifier listed that the decedent also suffered from diabetes, COPD, and smoked (note: this latter condition would also be checked in field 30, "Did tobacco use contribute to death?"). These circumstances are coexisting conditions that contributed to death, and although the conditions are risk factors for atherosclerotic coronary artery disease, they are not causes of atherosclerotic coronary artery disease. Thus, in a case such as this one, the conditions are most appropriately cited as other significant conditions.[30]

The distinction between Part I and Part II on a death certificate is important because multiple conditions and sequences of conditions resulting in death are common, particularly in the elderly or those who are very ill. Guidance from the CDC notes the following about the distinctions between Part I and Part II and its impact to the death coding process:[31]

> When there are two or more possible sequences resulting in death, or if two conditions seem to have added

[30] *See* Hanzlick, Randy, MD, FCAP. *Cause of Death and the Death Certificate*, College of American Pathologists, 2006.
[31] CDC. *Physicians' Handbook on Medical Certification of Death*, April 2003, p. 15.

> together, choose and report in Part I the sequence thought to have had the greatest impact. Other conditions or conditions from the other sequence(s) should be reported in Part II. For example, in the case of a diabetic male with chronic ischemic heart disease who dies from pneumonia, his certifying physician must choose the sequence of conditions that had the greatest impact and report this sequence in Part I. One possible sequence that the certifier might report would be pneumonia due to diabetes mellitus in Part I with chronic ischemic heart disease reported in Part II. Another possibility would be pneumonia due to the chronic ischemic heart disease entered in Part I with diabetes mellitus reported in Part II. Or the certifier might consider the pneumonia to be due to the ischemic heart disease that was due to the diabetes mellitus and report this entire sequence in Part I. Because these three different possibilities would be coded very differently, it is important for the certifying physician to decide which sequence most accurately describes the conditions causing death.

As shown above, the distinctions between Part I and Part II of a death certificate can be difficult to determine. In the end, however, the medical certifier must decide which factors most directly led to the death sequence and which factors were secondary. Statistically, mortality research focuses on the underlying cause of death because public health interventions seek to break the sequence of causally related medical conditions as early as possible. However, all cause information reported on death certificates is important and is analyzed.[32]

Medical Opinion/Judgment

Thus far, we have discussed the definitional distinctions between Part I and Part II on a death certificate and how this data furthers both administrative and public health needs. It is important to note that for most death certificates (the exception being where autopsies are performed), Part I and Part II are based on the informed medical opinion and judgment of the medical certifier. As such, there can be differences in opinions.

Per the CDC, medical certifiers are instructed as follows:[33]

[32] Ibid, p. 11.
[33] Ibid, p. 12.

> The cause-of-death information should be the physician's best medical OPINION. Report each disease, abnormality, injury, or poisoning that the physician believes adversely affected the decedent. A condition can be listed as ''probable'' if it has not been definitively diagnosed.

As shown by the above guidance, Part I and Part II are only looking for an opinion—not an absolute cause. Many people are often puzzled by this fact because they assume that because these sections are completed by physicians (or others with advanced medical training), the cause of death must be based on scientific proof, involving testing, medical records, or other post-mortem diagnosis.[34]

While this advanced sequencing may be done in some cases (e.g., homicides, unnatural deaths, etc.), the reality for most decedents is the opposite. Cause of death—and more specifically the sequence of immediate, intermediate, underlying, and contributing comorbidities—are all based on the certifier's medical opinion and judgment. Further, because the opinion is based on judgment, differences in opinion may exist.

Researchers we spoke with at the CDC/NCHS confirmed the lack of certainty with Part I and Part II of a death certificate, and they pointed us to research conducted on the accuracy of cause of death statements.[35] They noted that to conduct assessment on the accuracy of cause of death statements would require external data sources, such as autopsy or medical records, which are often unavailable or unlinked to death certificates. In addition, such evaluations (of death certificate accuracy) are not definitive because no truly objective measures of cause of death or a gold standard to use as the criterion for comparisons exists.[36] That being said, the researchers did look at the completeness of cause of death reporting.

[34] Research has shown that the public has a high opinion of physicians; thus, they may be more likely to trust their opinions generally. For example, according to the Pew Research Center, 74 percent of Americans have a positive view of medical doctors, only 8 percent had a mostly negative view. *See* https://www.pewresearch.org/science/2019/08/02/findings-at-a-glance-medical-doctors/. The nationally representative survey from Pew Research Center was conducted among adults ages 18 and older. About half of the survey respondents (N=2,238) were asked about medical doctors; these responses have a margin of sampling error of +/- 2.7 percentage points. Before answering questions about this group, respondents were given the following brief description: "Medical doctors provide patients with diagnoses of disease and/or treatment recommendations to promote, maintain or restore a patient's health."

[35] Leann Flagg, Ph.D. and Robert Anderson, Ph.D., National Vital Statistics Reports, *Unsuitable Underlying Causes of Death for Assessing the Quality of Cause of Death Reporting*, January 11, 2021.

[36] Ibid.

CDC/NCHS Findings on Suitability of Death Reporting. In an extremely complex and detailed review, researchers from the CDC/NCHS found that in 2018, 34.7 percent of deaths occurring in the fifty states and the District of Columbia had an underlying cause of death (UCOD) that is unsuitable.[37] Recall that the UCOD is the event or condition that starts the sequence of death and is the one that many researchers are most focused. The CDC/NCHS identified three types of unsuitability:

1. Deaths that had an unknown or ill-defined causes for the UCOD (e.g., listing a mechanism of death, such as cardiac arrest).

2. Deaths that had an immediate or intermediate cause as the UCOD (e.g., incorrect sequencing).

3. Deaths that had a nonspecific UCOD (e.g., listing cancer, but no specificity as to location or type).

Of the three types, nonspecific UCOD was the most common unsuitability found. The researchers also reviewed the information across states and places of death (e.g., hospital, nursing home, etc.). As shown in Exhibit 12, the results showed Pennsylvania to have a slighter worse than average ranking compared to the national average in all categories.

Exhibit 12

Unsuitability of Underlying Causes of Death
(United States and Pennsylvania)

	Total Deaths (2018)	(1) Unknown Ill-defined Causes		(2) Immediate and Intermediate as UCOD		(3) Nonspecific UCOD		Total Unsuitable UCOD	
		No.	Percent	No.	Percent	No.	Percent	No.	Percent
United States	2,846,305	61,678	2.2	362,293	12.7	563,808	19.8	987,779	34.7
Pennsylvania	**136,049**	**4,373**	**3.2**	**20,763**	**15.3**	**29,157**	**21.4**	**54,293**	**39.9**

Source: Developed by LBFC staff from information obtained from the CDC/NCHS.

As might be expected, unsuitability of UCOD also increased with age and with the type of facility reporting the death. According to the research,

[37] Ibid.

nationally, older adult age groups (65-84 and 85 and over) had the highest percentages of unsuitable UCODs at 33.8 percent and 45.0 percent, respectively.[38] Further, decedents who died in a nursing home or LTCF had the highest unsuitability rates at 43.1 percent nationally. Specific statistics were not available for Pennsylvania in these areas. However, given Pennsylvania's generally older population and higher LTCF resident population, this may explain why Pennsylvania exceeded national averages in general.[39]

We discussed these findings with the researchers at the CDC/NCHS and they added specific caveats with the analysis, as well some keen insights. They noted specifically the following:[40]

1. Unsuitable underlying cause of death does not mean that a death was reported erroneously or that the individual did not die from the condition stated. Rather, an unsuitable underlying cause of death is more an indication that the sequence of death was incorrect or incomplete because the certifier did not provide a specific underlying cause of death. In most instances of these unsuitable underlying causes, we believe that the diseases/conditions reported are correct. Most often, the problem is that the diseases/conditions are not reported with enough specificity, or they are not really underlying causes (i.e., the sequence is incomplete).

2. While standard deviations were not conducted, it is possible to make state-to-state comparison with the data. [We] agree that Pennsylvania was worse than the national average.

3. Unsuitable underlying cause of death reflects incomplete cause-of-death reporting on death certificates, not an error with the state's vital records systems, collection, and reporting to NCHS. The issue originates with the cause of death certifiers and what they report on death certificates. It is not with state vital records system or the coding process. That said, I do think there is potential for improvements that could be made by making changes in state systems and procedures.

[38] Ibid.
[39] DOH also believes that Pennsylvania's poor ranking for unsuitable UCOD is also directly related to Pennsylvania being ranked as one of the lowest states in regard to properly reporting drug overdoses.
[40] Email correspondence and interviews held in January and February 2021 with the chief, mortality statistics branch, and the lead health statistician at the CDC/NCHS.

We believe it is important to also emphasize these points. Although Pennsylvania performed worse than the United States average in unsuitable UCOD, that does not mean that these deaths did not occur or were incorrectly tabulated—rather, it means that the death reporting sequence was incorrect or lacked specificity. It also does not mean that medical certifiers are at fault. In many cases, medical certifiers are working with limited information, must make quick decisions about the death, and simply cannot provide the specificity desired. However, knowing that these occurrences do take place, places special significance in understanding how COVID-19 deaths are listed on death reports.

E. COVID-19 Cause of Death Reporting

COVID-19 is an underlying cause of death, not the immediate cause of death. As discussed in the last issue area, this means that when certifying a cause of death from COVID-19, it should be reported on the lowest line of Part I on a death report because it is a disease that starts the sequence of death. COVID-19 should never be reported as the immediate cause of death (i.e., line "a" of Part I) because it does not directly cause death. In simpler terms, COVID-19 is a disease that can bring about other life-threatening conditions, which result in death.

Guidance on COVID-19 Death Reporting

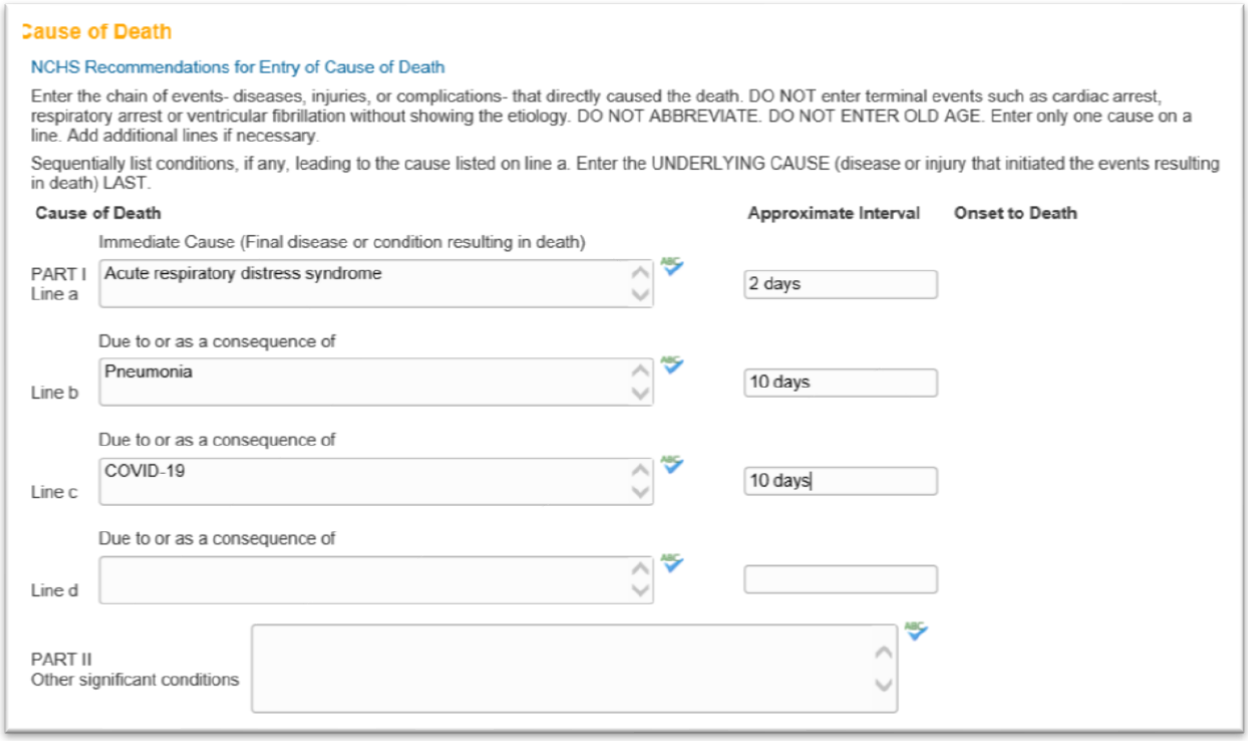
The CDC published guidelines in April 2020 for how medical certifiers should certify deaths from COVID-19.[41] This guidance reinforces the concepts discussed on the proper sequence of cause-of-death reporting. DOH adopted this guidance and expanded upon it through State Registrar Notices (SRN) released throughout 2020. For example, DOH published SRN 2020-01 on March 16, 2020 (further revised on April 16, 2020). This SRN outlined the reporting process for deaths from COVID-19 and mandated that all deaths from COVID-19 must be reported through EDRS. Within this guidance, DOH also established that the manner of death for COVID-19 deaths shall be reported as "natural" unless circumstances surrounding the death suggest that the death was sudden, violent, suspicious in nature, or was the result of other than natural causes. In non-natural cases, the case is to be referred to the county coroner or medical examiner.[42]

Exhibit 13 depicts how a typical COVID-19 death might be certified by a physician. The exhibit also uses screen images from the EDRS system.

[41] CDC/NCHS, Guidance for Certifying Deaths Due to Coronavirus Disease 2019 (COVID–19), April 2020.
[42] See State Registrar Notice 2020-01, "COVID-19 for Medical Professionals." Similar notices were also published for coroners, funeral directors, and registrars (SRN 2020-02, SRN 2020-03, SRN 2020-04, respectively).

Exhibit 13

COVID-19 Cause of Death Reporting
Hypothetical Case Example



Cause of Death

NCHS Recommendations for Entry of Cause of Death

Enter the chain of events- diseases, injuries, or complications- that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. DO NOT ENTER OLD AGE. Enter only one cause on a line. Add additional lines if necessary.

Sequentially list conditions, if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE (disease or injury that initiated the events resulting in death) LAST.

Cause of Death		Approximate Interval	Onset to Death
	Immediate Cause (Final disease or condition resulting in death)		
PART I Line a	Acute respiratory distress syndrome	2 days	
	Due to or as a consequence of		
Line b	Pneumonia	10 days	
	Due to or as a consequence of		
Line c	COVID-19	10 days	
	Due to or as a consequence of		
Line d			
PART II Other significant conditions			

Source: Developed by LBFC staff from SRN 2020-01.

As shown in the above example, COVID-19 is listed as the underlying cause of death. In turn, COVID-19 lead to pneumonia (the intermediate cause of death), which in turn caused acute respiratory distress and death. Again, the key distinction here is that COVID-19 is listed as the underlying cause of death, not the actual immediate cause of death. Further, in this example it is assumed that there would have been a laboratory test completed for listing COVID-19 as the underlying cause of death.

SRN 2020-13. As the pandemic continued through the spring and summer of 2020, DOH issued additional guidance regarding COVID-19 death reporting. SRN 2020-13 issued on April 8, 2020, and amended on October 8, 2020, provided supplemental information to medical professionals about reporting COVID-19, stating that:

> ***COVID-19 should be reported for all decedents where the disease caused or is assumed to have caused or***

> ***contributed to death***. Medical professionals should include as much detail as possible based on knowledge of the case, medical records, laboratory testing, etc. If the decedent had other chronic conditions such as COPD or asthma that may have contributed, these conditions can be reported in Part II.
>
> ***COVID-19 should not be included on the report of death if it did not cause or contribute to the death***.

This guidance clearly indicates DOH's intention that COVID-19 should only be reported on a death record when the disease caused or is assumed to have caused or contributed to death. In fact, DOH reiterated this point by stating in bold print that if the disease did not cause or contribute to the death, it should not be reported.

SRN 2020-13 continued by providing further guidance on when and how to report confirmed, pending, and probable deaths from COVID-19. Briefly, these distinctions mean the following:

> **Confirmed**. The decedent had a laboratory confirmed case of COVID-19.
>
> **Pending**. The decedent died while laboratory test results were pending. In these cases, medical certifiers were to report "pending COVID-19 test results" and then after the results were received, an amendment to the death record was to be made via EDRS (i.e., confirming or changing the cause of death).
>
> **Probable**. The decedent died and it is assumed that COVID-19 caused or contributed to the death, but there is no laboratory confirmation, and none is pending. In these situations, DOH stated that terminology such as "probable COVID-19" or "likely COVID-19" may be used as the underlying cause of death.

The differences between these underlying causes of death may seem apparent, but it may have created confusion for certifiers, especially when getting into the nuances of "presumed," "pending," "probable," etc. For example, as one coroner stated to us about EDRS, "doctors are busy people, and don't always have the time to read and learn about registrar notices." This comment is confirmed by other research, which noted that when emergency room and intensive care unit physicians are dealing

with crowded facilities and increasing patients, death certificates are not a priority.[43]

Interestingly, SRN 2020-13 further provided examples of terms that should not be used in COVID-19 cases, such as:

- Non-specified strains of coronavirus. Medical professionals are required to include the strain of coronavirus.
- Possible COVID-19 exposure.
- COVID-19 Ruled out or COVID-19 R/O.
- COVID-19 Negative.
- Mechanism of death, such as cardiac arrest and respiratory failure.
- Patient care directives, such as do not resuscitate (DNR) or comfort care.

Dying from COVID-19 and Dying with COVID-19

Up to this point, we have outlined and described the intricacy between cause of death reporting, generally, and specifically, COVID-19 death reporting. However, there is another important variable, the difference between dying ***from*** COVID-19 and dying ***with*** COVID-19. This distinction impacts COVID-19 death counts but is also an important factor in disease surveillance.

From a disease surveillance perspective, it is important to capture as much information as possible about the disease. This process involves test results from laboratories (e.g., tracked through PA-NEDSS) and death certificate information (vital records). In the latter cases, guidance issued by the CDC through the Council of State Territorial Epidemiologists (CSTE)[44] stated that for vital records tracking, any person whose death certificate lists COVID-19 as cause of death (Part I) or a significant condition contributing to death (Part II) should be tracked and reported as an infectious disease.[45] DOH follows this guidance, and as a matter of practice reports a COVID-19 death (from vital records) as one where COVID-19 appears anywhere in Part I or Part II of a death record. This includes COVID-19 deaths that have been laboratory-confirmed or clinically confirmed.

[43] Knight and Appleby, "How Covid Death Counts Become the Stuff of Conspiracy Theorists," *Kaiser Health News*, November 2, 2020.
[44] CSTE is an organization of member states and territories representing public health epidemiologists. CSTE works to establish more effective relationships among state and other health agencies. It also provides technical advice and assistance to partner organizations and to federal public health agencies such as the Centers for Disease Control and Prevention. CSTE members have surveillance and epidemiology expertise in a broad range of areas including occupational health, infectious diseases, environmental health, chronic diseases, injury, maternal and child health.
[45] Council of State and Territorial Epidemiologists, Interim-20-I-01.

While this is a standard practice advocated by the CDC/NCHS, and most states follow this guidance, confusion results when trying to count COVID-19 deaths as being an underlying cause of death, or a contributing factor to death. In these cases, the specific nuances of the case, as well as the medical opinion of the certifier play a significant role.

For example, per DOH guidance (SRN 2020-13), and consistent with guidance from the CDC/NCHS, COVID-19 should not be reported on the death certificate unless it directly caused (Part I) or contributed (Part II) to the death. To demonstrate this nuance, assume for illustrative purposes that an individual dies from an automobile crash and is COVID-19 positive. In this scenario, although the individual is COVID-19 positive, the death report should not include COVID-19 (or any other medical conditions) as the cause of death because the death was not caused, nor contributed to by those other conditions.

Continuing with the above example, however, assume that while driving the automobile, the individual passed out from coughing because of a COVID-19 infection. In this situation, then it would be reasonable to list COVID-19 on the death report because if not for the disease, the individual would not have lost consciousness and crashed.[46] In this case scenario, this case would be counted as a COVID-19 death, if the medical certifier listed COVID-19 on the death report.

One can imagine the infinite number of possibilities that could arise when trying to count deaths and whether the deaths were from or with COVID-19. This begins to create "grey" areas where opinions may differ. For example, given that COVID-19 is a new disease, not all health-related linkages are entirely apparent. Research continues to evolve on the short-term and long-term effects of the disease on major organs of the body, which can lead to strokes and other bodily damage.[47] This point again emphasizes the importance of medical certifiers using the correct and appropriate sequence of events and conditions on a death report.

On the matter of dying with COVID-19 and dying from COVID-19, we also spoke with a non-statistical sample of funeral directors from across the state.[48] These funeral directors cited their personal experiences in

[46] Early in the pandemic there were multiple media reports and various theories surrounding these types of cases. A similar example was reported in Berks County. Media outlet WUSA9 investigated this case, and spoke with the health care officials, including the county coroner. Investigators verified that the death was not related to the vehicle crash and the individual did have a coughing episode which caused him to lose consciousness. *See* https://www.wusa9.com/article/news/verify/covid-deaths-car-crash-comorbidities-coronavirus-death-total-counts-john-hopkins-study/65-e3842ed2-f753-4a15-8b97-c2ae75c2b2ce.

[47] *See* https://www.mayoclinic.org/coronavirus-long-term-effects/art-20490351, accessed April 8, 2021.

[48] Interviews were conducted in February 2021 of six funeral directors, who operated funeral homes in rural and urban areas across Pennsylvania. Each of the directors had personal experience in processing COVID-19 death reports through EDRS. The interviews were coordinated with assistance from the Pennsylvania Funeral Directors Association.

reviewing and submitting COVID-19 death reports. All the directors we interviewed cited instances of death reports where the cause of death was incomplete or illogical. For example, anecdotal examples were cited of COVID-19 being listed as a comorbidity, when it seemed obvious to them that the death was unrelated to COVID-19. In fact, one director in the Harrisburg area estimated that as many as 60 percent of the COVID-19 death reports that came to their funeral home had sequence of death errors. In their collective opinions, this condition was a result of lack of training on the behalf of medical certifiers and/or difficulty in getting certifiers to complete their portions of the death report timely.

We caution there are important caveats to this discussion. First, funeral directors are not licensed physicians, nor medical certifiers. As a result, while their experiences are valuable, the viewpoints should not be considered to be expert opinions about cause of death reporting. Second, funeral directors are only reviewing one aspect of the death report, which is typically part of the pre-registration control process. The underlying death record may continue to be amended (i.e., corrected) as part of the post registration control process, which funeral directors may not see. Stated differently, although funeral directors may notice errors on the front-end of the death registration process, they may not always see amendments that are being created after registration with DOH.

Finally, regarding dying with COVID-19 or dying from COVID-19, it is important to mention that each state may have a slightly different methodology in counting these deaths. For example, in Colorado in May 2020, the COVID-19 death count was changed by 300 deaths, when officials decided to change its methodology by excluding certain deaths where COVID-19 was not a factor in the death.[49] Colorado now reports a distinction between dying with COVID-19 and dying from COVID-19.

In another example, Illinois, which uses a broader definition and counts all deaths, the state director of health noted the following:[50]

> If you were in hospice and had already been given a few weeks to live, and then you also were found to have COVID, that would be counted as a COVID death. It means technically even if you died of a clear alternate cause, but you had COVID at the same time, it's still listed as a COVID death. So, everyone who's listed as a COVID death doesn't mean that that was the cause of the death, but they had COVID at the time of the death.

[49] Larsen, Eric, "Did Colorado's coronavirus death toll really drop by nearly 300? Here's what changed." Fort Collins Coloradian, May 16, 2020.
[50] Statement from Dr. Ngozo Eziek, Director, Illinois Department of Health, April 20, 2020. See https://week.com/2020/04/20/idph-director-explains-how-covid-deaths-are-classified/

The end analysis of this discussion is that it can be very confusing to count deaths from (or with) COVID-19. From an epidemiological standpoint, whether COVID-19 shortened a life by 15 days or 15 years, or whether it was an underlying condition, or a contributing condition—it should be reported so that researchers can learn about the overall impact of the virus. This point may lead some to conclude that COVID-19 deaths are over-reported. However, the consensus among experts is that COVID-19 deaths are undercounted because of a lack of testing in the early days of the pandemic.[51] As stated by the Mortality Statistics Director at the CDC/NCHS, "It will take some time to know the exact number of deaths, but this official number will be based on information collected on death certificates."[52]

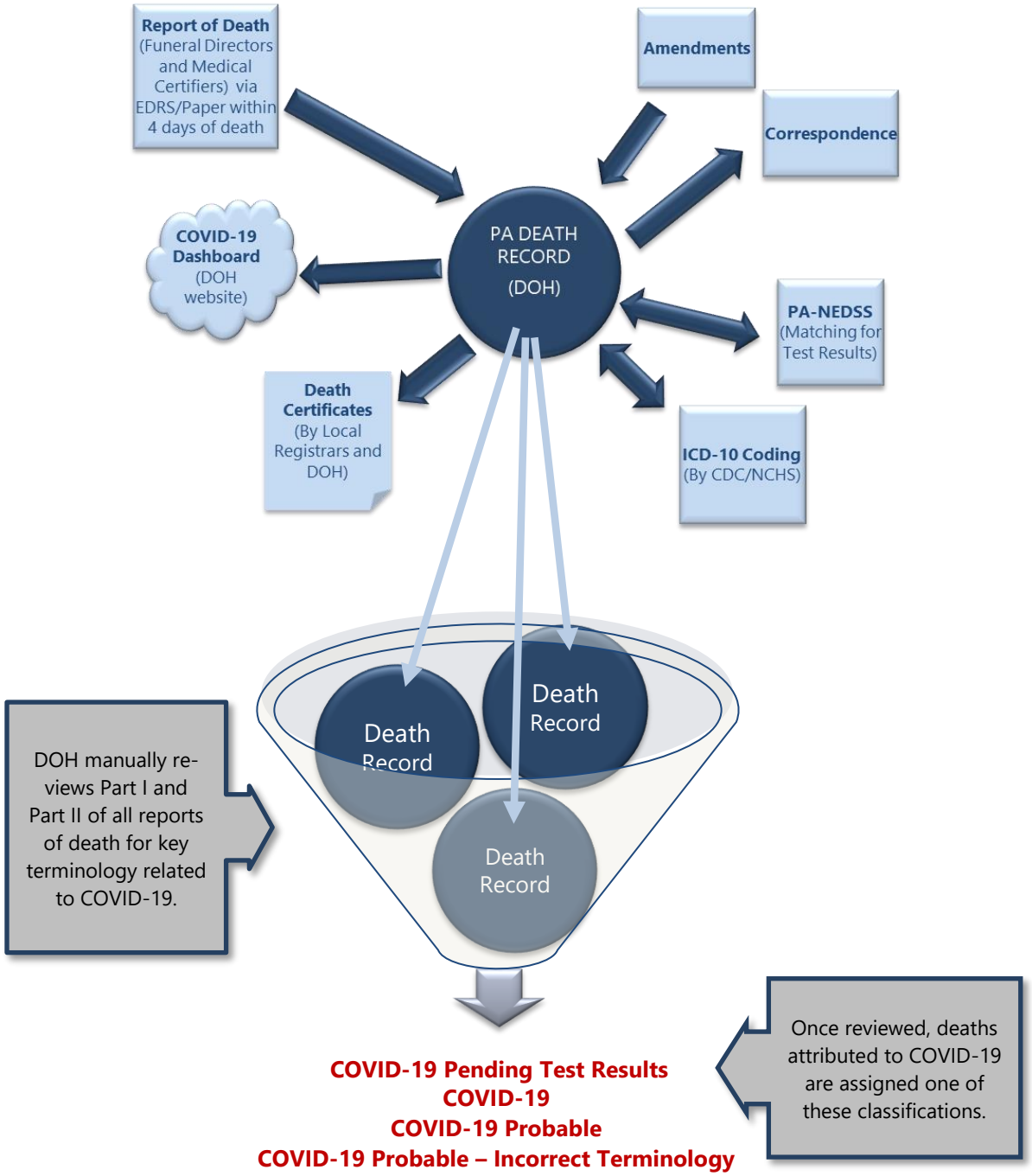
DOH Methodology for Counting COVID-19 Deaths

As discussed earlier, DOH presents several different and sometimes conflicting data sources related to COVID-19 deaths. However, for data which is published to the COVID-19 dashboard, provided in daily updates, or published in the weekly report of COVID-19 deaths, DOH relies upon data from death records. DOH methodology follows guidance from the CDC/NCHS and identifies a COVID-19 death as one where COVID-19 (confirmed or probable) is listed as either an underlying cause (Part I) or listed as a contributing cause (Part II). In other words, whether a decedent dies *with* or *from* COVID-19, the death is counted as a COVID-19 death. Exhibit 14 depicts how DOH reaches these internal classifications.

[51] Boyle, Patrick. "How are COVID-19 Deaths Counted? It's Complicated," Association of American Medical Colleges, February 21, 2021.
[52] Ibid.

Exhibit 14

DOH Classification of COVID-19 Deaths



Source: Developed by LBFC staff from information provided by DOH.

Using our earlier exhibit depicting the death record workflow, for COVID-19 deaths an additional step is added once DOH receives the record. That step involves a manual review of cause of death statements (Part I) and any additional contributing factors (Part II) by staff from DOH's Bureau of Health Statistics and Registries. In conducting these reviews, staff are searching for key terminology used to indicate a possible COVID-19 related death. For example, DOH informed us that staff will query Part I and Part II fields for terms such as:

- COVID-19,
- COVID-19 probable,
- Coronavirus 19,
- likely COVID-19,
- SARS-CoV-2,
- Novel Coronavirus.

As "hits" are returned from these searches, the death is reviewed closer, including checking for possible COVID-19 test results in PA-NEDDS. Once completed, the death is then labeled with an "internal DOH classification,"[53] which is one of one of four types:

- COVID-19 Pending Test Results,
- COVID-19,
- COVID-19 Probable,
- COVID-19 Probable-Incorrect Terminology.

Only deaths that have been labeled as COVID-19, COVID-19 Probable, and COVID-19 Probable-Incorrect Terminology are included in DOH's death count. Any terminology indicating that test results are pending, are labeled as "COVID-19 Test Results Pending." These deaths are <u>not</u> included in the COVID-19 death counts. Only after the record has been amended to indicate that the death was attributed to COVID-19 (based on test results) would the death be included in DOH's count.

Excess Deaths

As a final point about COVID-19 cause of death reporting is a brief discussion of "excess deaths" and how this evaluation can provide additional context about death reporting. According to the CDC, estimates of excess deaths can provide information about the burden of mortality (e.g., potentially related to the COVID-19 pandemic), including deaths that are directly or indirectly attributed to COVID-19. Excess deaths are typically defined as the difference between the observed number of

[53] Note: The classification assigned by DOH does not change based on CDC/NCHS review..

deaths in specific time periods and the expected number of deaths in the same time periods.[54]

Because many deaths due to COVID-19 may be assigned to other causes of death (for example, if COVID-19 was not mentioned on the death report as a suspected cause of death), tracking "all-cause mortality" provides information about whether an excess number of deaths is observed, even when COVID-19 deaths may be undercounted. These estimates can also provide information about deaths that may be indirectly related to COVID-19. For example, if deaths due to other causes increase because of health care shortages due to COVID-19.

With data we obtained from the CDC/NCHS and DOH, we conducted a rudimentary "excess death" analysis for calendar year 2020.[55] We analyzed the CDC/NCHS estimate for Pennsylvania's weekly average expected count of deaths. This figure includes deaths from all causes and averages various thresholds to present a "best guess" of what the expected count of deaths would be.[56] We then compared that figure to the report of "registered deaths" for calendar year 2020, which are DOH's provisional death counts (i.e., not final). The results are presented in Exhibit 15 on the following page.

[54] *See* https://www.cdc.gov/nchs/nvss/vsrr/covid19/excess_deaths.htm

[55] Note: The CDC/NCHS conducts estimates of excess deaths on a weekly basis, using complex algorithms and other statistical models. Per the CDC, estimates of excess death can be calculated in a variety of ways, and will vary on the methodology and assumptions about how many deaths are expected to occur. Data we used in our analysis are based on provisional death counts; therefore, the data is subject to change.

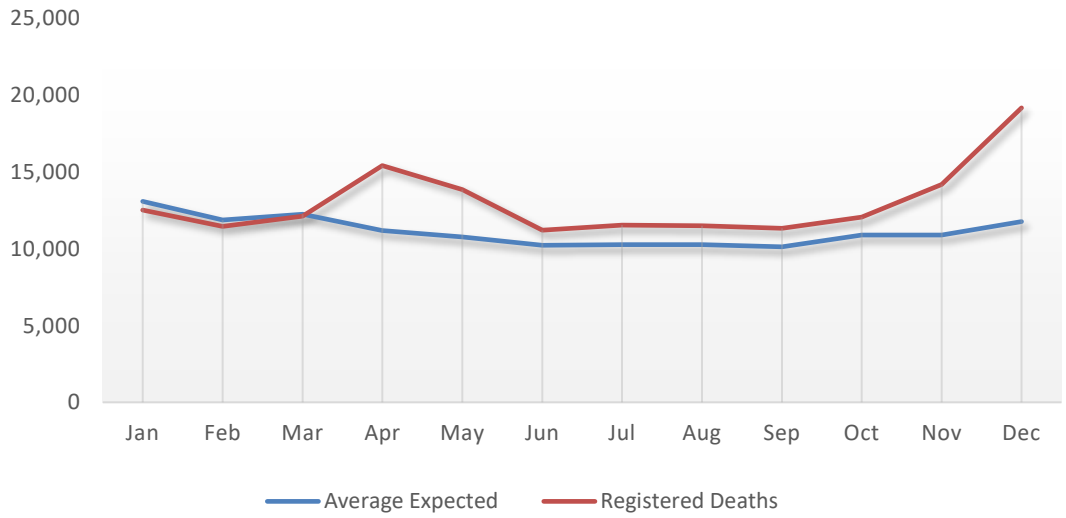
[56] Because the CDC develops weekly estimates and we had monthly data from DOH, we prorated some CDC data between months. For example, where a week was split between two months.

Exhibit 15

2020 Excess Death Comparison

Month	Average Expected*	Registered Deaths (Provisional)	Percent Inc/Dec Between Expected and Registered Deaths
January	13,088	12,522	-4.3
February	11,877	11,459	-3.5
March	12,245	12,125	-1.0
April	11,188	15,429	37.9
May	10,764	13,851	28.7
June	10,227	11,213	9.6
July	10,275	11,537	12.3
August	10,265	11,496	12.0
September	10,130	11,337	11.9
October	10,893	12,066	10.8
November	10,888	14,180	30.2
December	11,778	19,178	62.8
Total	**133,618**	**156,393**	**17.0**

Trend of Expected and Registered Deaths CY 2020



Note: Data comparisons are based on provisional counts and are continuing to be revised.
Source: Developed by LBFC staff from data obtained by the CDC and provided by DOH.

As shown in the above Exhibit, during the first quarter of 2020, the number of registered deaths trailed the CDC's estimate of expected deaths. This trend changed as the pandemic took hold of Pennsylvania in March and April and infections increased. Because deaths lag infections, this

trend explains why large increases were observed in April and May (37.9 percent and 28.7 percent, respectively).

As shown in the line graph, although registered deaths continued to exceed the average expected deaths through the summer and early part of the fall, as Pennsylvania experienced a second wave of COVID-19 cases in the fall, deaths also significantly increased in November and December of 2020 (30.2 percent and 62.8 percent, respectively).

Overall, for CY 2020, Pennsylvania saw 22,775 "excess deaths" or an increase of 17 percent from the expected deaths. We urge extreme caution though in assigning these numbers as all COVID-19 deaths. Most importantly, the expected averages are based on complex algorithms, which can be heavily influenced by reporting lags and other factors. Although the CDC/NCHS attempts to factor for these issues, they do note the following:[57]

> These estimates are based on provisional data, which are incomplete. The weighting method applied may not fully account for reporting lags if there are longer delays at present than in past years.

In the end, there are additional factors that need to be considered as well, e.g., weather, other seasonal patterns, etc. Nevertheless, we believe this analysis, although rudimentary, does provide additional perspective to show the effect COVID-19 has had on mortality tabulations.

RECOMMENDATIONS

This study is the first of several studies related to COVID-19 data reporting. We anticipate additional recommendations that will evolve from our ongoing review and research. However, from this initial review, there are two areas that require immediate attention. Those areas are:

1. **DOH needs to improve its data collection and presentation on its website**. COVID-19 data on DOH's website, while plentiful, needs better descriptions of its source and where and why it may conflict with other presented data sources. Some states, like Oregon, Wisconsin, and Alaska, to name three specific examples, provide detailed descriptions of where death data is collected, how the collection process works, and why fluctuations may be apparent. Wisconsin includes YouTube videos with relevant state experts explaining the details of its data collection and reporting procedures. DOH needs to improve upon its data definitions and in clear terms explain the significance of the data to end-users. Further, and most importantly,

[57] See "Limitations" at https://www.cdc.gov/nchs/nvss/vsrr/covid19/excess_deaths.htm

DOH needs to resolve the inconsistent reporting that is apparent in long-term care facility data.

2. **DOH should monitor the accuracy in cause of death reporting through, in part, the creation of a task force of stakeholders to address ongoing issues**. Cause of death reporting was an issue area prior to the pandemic. Since the pandemic, the need for accurate COD reporting has been emphasized. DOH should form and lead a taskforce of stakeholders, which at a minimum would include representatives of coroners, physicians, funeral directors, and medical schools. The taskforce should work to identify a plan to address issues including, but not limited to, the following:

    a. Communication barriers between parties involved in reporting deaths.
    b. Information technology solutions and best practices.
    c. Curriculum enhancements for medical professionals on death reporting/cause of death reporting.
    d. Need for continued education training opportunities for medical certifiers and others on death reporting.
    e. Development of a "data quality" team to semi-annually monitor the suitability of cause of death reporting in Pennsylvania.

SECTION IV – REVIEW OF COVID-19 DEATH RECORDS

Fast Facts…

- *Our work in this section includes a scope limitation and impairment because DOH denied access to information we requested—death certificates/records. We strongly disagree with DOH's position based on its interpretation of the law.*
- *DOH provided a data file of 17,834 records, which represented deaths the agency had internally assigned various COVID-19 death classifications, as well as the CDC/NCHS coding of the underlying cause of death.*
- *Of the 17,834 records, the CDC/NCHS coded 1,596 records as something other than COVID-19. This difference is likely the result of the source used in making the determination—e.g., Part I or Part II of the death record. Because we lack access to the death records, we cannot prove this assumption. We intend to revisit this issue.*

Overview

Our primary objective for this first report was to "review death certificates for citizens who may have died from COVID-19 to ensure the deaths were properly, accurately, and consistently reported to the Department of Health (DOH)." As we discussed in Section III, death certificates are created from the underlying death record, which is maintained by DOH. Unfortunately, DOH has denied us access to information necessary to answer the objective, specifically death certificates from the underlying death record.

As we discussed in earlier sections, the VSL is the Commonwealth's record keeping and enforcement statute, which designates DOH as the custodian of all vital record information. The VSL rightly protects vital record information from release, but the law does allow DOH to share the information with government agencies and permits the use of the information for research. DOH has made the legal conclusions, however, that the LBFC is not an "agency of government," under the language of the VSL, and our work is not official work. Further, DOH Counsel concluded that our work for this study was outside the boundaries of what they determined to be research under the language of the VSL; thus, DOH was further precluded from providing us with the vital record information we sought.

We strongly disagree with DOH's legal conclusions on all accounts. We sought a reconsideration of DOH's conclusion, but to date, there has been no change to their position.

Because we were denied access to the information we requested (death certificates and death records), we have issued a scope limitation and impairment for our work. In simple terms, this designation means that we attempted to answer a research question (our study's objective), but, in our opinion, the limitations imposed upon our access to needed information impairs our ability to gather sufficient and appropriate evidence to answer the objective. We will continue to seek alternatives to DOH's position on the VSL, and we hope that future reviews will allow us the unfettered access that we believe is allowed by the VSL and necessary to complete our work under HR 1087.

In the interim, we worked with DOH to obtain highly redacted information about COVID-19 deaths. DOH provided us with a data file containing all deaths for which the agency had assigned an internal classification as either COVID-19, COVID-19 Probable, or COVID-19 Probable – Incorrect Terminology. A fourth classification called "COVID-19 Pending Test Results" is also used when the case is believed to be a COVID-19 death, but test results are needed to confirm. These latter cases are not reported as COVID-19 cases until the death record has been amended to indicate a positive COVID-19 test.[58] Included with the data file was the CDC/NCHS' determination of the underlying cause of death.

The data file we obtained contained 17,834 records for deaths which occurred as of December 31, 2020. Of that number, the overwhelming majority (98 percent) had been internally classified as "COVID-19" deaths. Fewer than two percent were assigned "COVID-19 Probable," and very few—approximately 0.2 - percent were assigned as "COVID-19 Probable – Incorrect Terminology." In these latter cases, reviewers assigned this status because either Part I or Part II of the death certificate used incorrect terminology, such as misspellings or incorrect acronyms.

Our only source of corroborating evidence for these deaths (as well as a source for additional demographic detail) was from DOH's Weekly Report of COVID-19 Deaths. We used this report, as of December 31, 2020, as a basis for demographic information about COVID-19 deaths. This report, however, contains 15,978 records. The difference between this report and the data file supplied to us is due to the timing between when the reports were generated. The weekly report showed that nearly 58 percent of COVID-19 deaths were among those aged 80 and older, with the largest frequency of deaths occurring among those aged 85-89. Finally, with respect to this dataset, we also looked at comorbidity data and found that cardiology-related issues (hypertension, coronary artery disease, etc.) was the largest grouping of comorbidities listed.

Lastly, with respect to the 17,834 records we received from DOH, we further reviewed that data file and found that 1,596 records had been coded by the CDC/NCHS with an underlying cause of death as something <u>other</u> than COVID-19. This does not mean that the deaths were <u>not</u> to be counted as COVID-19 deaths. Rather, we believe the discrepancy is explained by how deaths are counted. For disease surveillance purposes (and per CDC/NCHS guidance) DOH counts COVID-19 deaths broadly, i.e., COVID-19 appearing anywhere on Part I or Part II of the death record. However, the data DOH supplied to us from the CDC/NCHS, is just the underlying cause of death as determined from Part I of the death record. This problem is akin to the issue of trying to count deaths dying *with* COVID-19 and/or dying *from* COVID-19. We would have reviewed these records closer to determine if in fact our conclusion was correct

[58] DOH indicated that the record could also be amended to indicate Probable COVID-19.

and investigate any other anomalies, but because DOH denied us access to the corresponding death certificates/records we can only provide limited analysis. For example, of the 1,596 records that did not have COVID-19 as an underlying cause of death, 518 were related to diseases of the circulatory system.

Issue Areas

A. Scope Limitation and Impairment

According to Government Auditing Standards issued by the United States Government Accountability Office (GAO), through the Comptroller General of the Unites States, scope is defined as follows:[59]

> **Scope**: The boundary of the audit and is directly tied to the audit objectives. The scope defines the subject matter that the auditors will assess and report on, such as a particular program or aspect of a program, the necessary documents or records, the period of time reviewed, and the locations that will be included.

Stated differently, scope is the "four corners" of the audit. It determines the start and stop of the review, and determines what information is needed to answer the question (i.e., audit objective) under review.

As discussed in the Objectives, Scope, and Methodology section of this report, our objective was to review death certificates for citizens who may have died from COVID-19 to ensure the deaths were properly, accurately, and consistently reported to DOH. Our scope obviously included reviewing a selection of death certificates (the product of the underlying registered death record), and specifically, death certificates of individuals who died from COVID-19.

As we planned our work for this project, we had several questions about death reporting within the state, and externally to the CDC/NCHS. Our queries included, but were not limited to, the following:

1) Are cause of death statements accurately and consistently reported?

2) Where did the person die (home, hospital, long-term care facility), and how are those deaths counted?

[59] Paragraph 8.10, Government Auditing Standards: 2018 Revision, Technical Update April 2021.

3) Was the COVID-19 death confirmed by testing or clinical diagnosis?

4) How does the CDC/NCHS review and count Pennsylvania-based COVID-19 deaths?

Our basis for seeking answers to these questions are largely outlined in Section III of this report. For example, we knew that EDRS was recently mandated for all COVID-19 death reports. Given the urgency in this decision, we believed there was a higher risk for errors. From discussions with coroners and funeral directors, we also heard concerns about the accuracy of cause of death statements. These concerns were accentuated by Pennsylvania's rather poor rating in the unsuitability of underlying cause of death research conducted by the CDC. Further, accessing information about COVID-19 deaths from DOH's website was confusing and often contradictory. For these reasons, our professional skepticism, which we use in making assessments about methodology for obtaining sufficient and appropriate evidence, was raised.

Through discussions with DOH staff and its legal counsel, we had hoped to broker an agreement whereby DOH would provide us with redacted copies of death certificates, specifically Part I and Part II from a random selection of decedents whose death certificates indicated that they had died from COVID-19 during calendar year 2020. From there, we intended to see if the sequence of death was accurate or consistent, and whether other reporting anomalies were present in our initial selection.

While the information we sought is generally confidential under the state's 1953 Vital Statistics Law (VSL), the VSL provides exceptions to that confidentiality. The VSL allows DOH to share the information with government agencies doing their work and permits the use of the information for research. DOH denied our request. DOH has taken the position that our request fell outside the allowed statutory exceptions. As outlined in correspondence to the LBFC Executive Director (see Appendix B), DOH has made the legal conclusions that:

- The LBFC is not an "agency of government."
- The LBFC's work is not "in the interest of conduct of official duty."
- The LBFC's work in studying and analyzing the reporting of death records in the Commonwealth is not "research."

We strongly disagree with DOH's position on these matters and presented an alternative interpretation of the law with which DOH disagrees. While we recognize the custodial duties placed upon DOH to preserve

and protect vital records, DOH's legal conclusions appear to exceed the scope of DOH's custodial duties and obstruct the permitted access we believe is intended under Sections 805 and 806 of the VSL.

For example, from a common sense and good governance perspective, data sharing between governmental components is helpful. In drafting the VSL, the legislature clearly anticipated scenarios in which the confidentiality restrictions could be lifted so that other governmental components could rely upon data maintained by DOH.

LBFC Counsel provided an appropriate rebuttal to DOH's Counsel's decision and sought a reconsideration of their conclusion (see Appendix C). To date, DOH has not reconsidered our request; consequently, we are essentially left at a stalemate.

DOH was willing to provide us with limited provisional data related to COVID-19 deaths. Specifically, DOH provided us with its internal COVID-19 death classification status, as determined from its review of death records, as well as the CDC/NCHS' determination of the underlying cause of death from that agency's review. Although we believe the VSL permits us full access to vital record information, to keep this project on schedule, we agreed to review and use DOH's data. We intend to revisit this ongoing dispute over access to records in future reviews.

B. Review of DOH's COVID-19 Death Data

As discussed above, we received a data file from DOH which contained 17,834 records. These records, sadly, represented individuals, all of whom DOH had classified for reporting purposes as perishing from COVID-19 during calendar year 2020. We do not know the specifics of these individuals or the sequence of events that caused their deaths. Nevertheless, we used this data, along with limited corroborating evidence obtained from DOH's Weekly Report of COVID-19 Deaths, dated December 31, 2020, to present a contextual reference of COVID-19 morbidity in Pennsylvania.

DOH Internal Classifications

As we presented in Section III, we know that as death records are registered, DOH staff review both Part I and Part II for terminology indicating a COVID-19 death. Once identified, DOH then assigns a classification of one of the following:

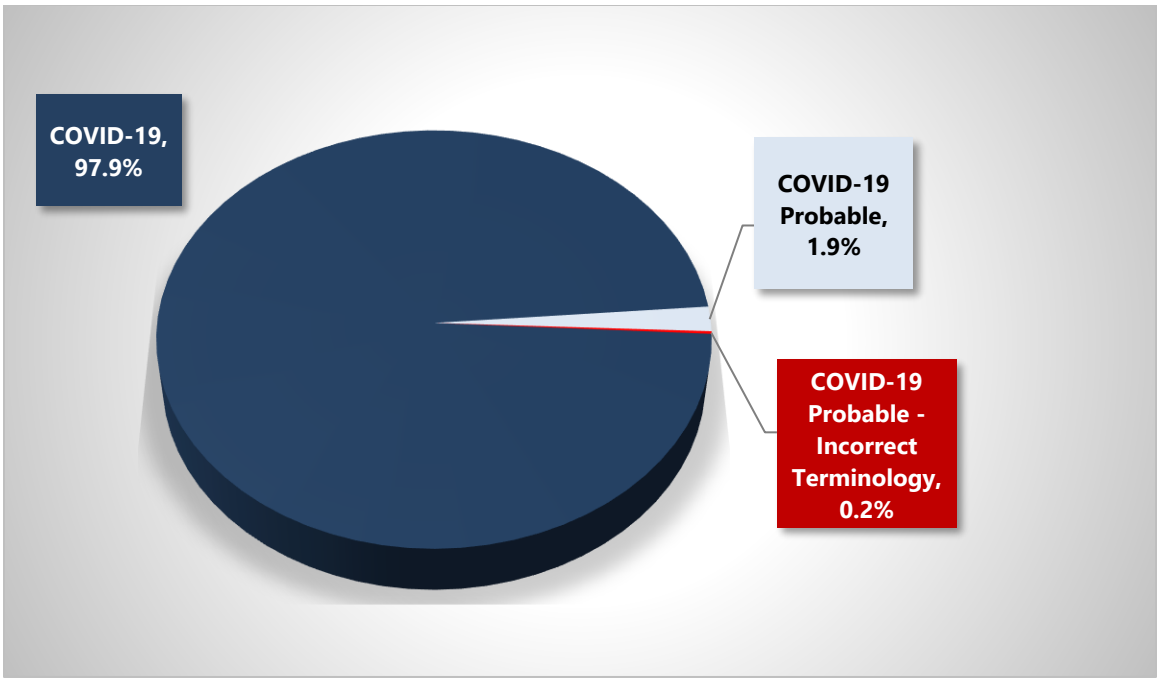
1. COVID-19
2. COVID-19 Probable

3. COVID-19 Probable – Incorrect Terminology
4. COVID-19 Pending Test Results

Only the first three classifications are reported to the public as deaths from COVID-19. And, for the fourth category, the death is counted as being a COVID-19 death, if the record has been amended to indicate positive or probable at which time the record is reviewed again by DOH. As shown in Exhibit 16, we reviewed the 17,834 records and found the following:

Exhibit 16

DOH Internal Classifications of COVID-19 Deaths
(CY 2020)
n= 17,834



Source: Developed by LBFC staff from information provided by DOH.

The data file we received from DOH contained no deaths with an internal classification of COVID-19 Pending Testing results; consequently, at this point, we are unable to present how many additional cases there may be to add to the total. Overwhelmingly, by a margin of nearly 98 percent (17,460 of 17,834 total deaths), DOH has classified these deaths as "confirmed" COVID-19, meaning that a lab test confirmed that the decedent had COVID-19, and that it was listed on either Part I or Part II of the death record. Additionally, approximately 2 percent of the deaths (339)

were probable COVID-19 deaths. Only a very slim margin of the deaths, just 0.2 percent, were internally classified as "COVID-19 Probable - Incorrect Terminology." This classification is used where DOH reviewers found that the death was a result of COVID-19, but the medical certifier may have used incorrect terminology, such as misspellings or incorrect acronyms.

We attempted to reconcile the 17,834 deaths above to the "Weekly Report for Deaths Attributed to COVID-19" for December 31, 2020. In that weekly report, DOH listed 15,978 registered deaths from COVID-19, which is 1,856 fewer deaths than the data file we received. We attributed this difference to the timing lag (see Section III) between when these data runs were prepared. For example, the weekly report would have only captured deaths that had been registered as of 11:59 p.m., on December 30, 2020. However, the data file above would include all those deaths, plus any deaths that occurred in 2020, but had not been registered until March 18, 2021. DOH confirmed this understanding, but also noted that the increase was due to amendments to deaths registered by December 31, 2020, where COVID-19 was not listed as contributing to the death. Such cases include those reported as pending investigation by medical examiners/coroners, who then later amended the death record to list COVID-19 as the final cause of death.

Detail from DOH's Weekly Report of COVID-19 Deaths, December 31, 2020

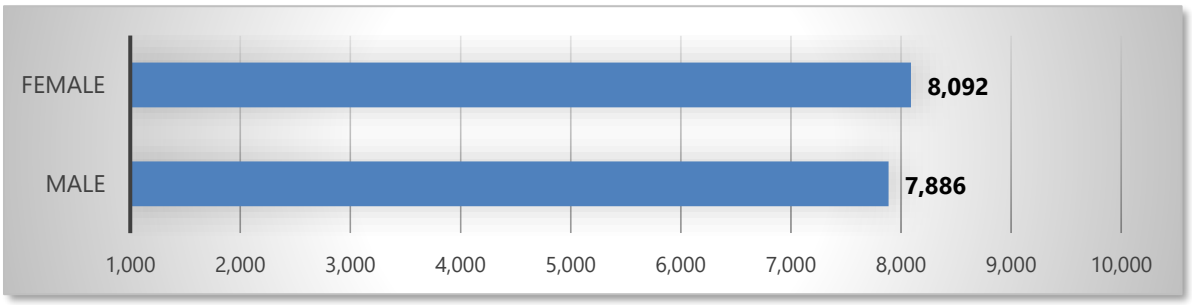
Because we lacked detailed data from DOH about COVID-19 deaths, our best alternative was to review information from DOH's Weekly Report of COVID-19 Deaths, dated December 31, 2020 (Weekly Report). This report lists various demographic and other related information about registered COVID-19 deaths. There is a significant caveat in using this data. Because we could not review and test the supporting documentation, we are unable to provide any degree of certainty about its overall accuracy. Therefore, this presentation is for contextual purposes only. Moreover, as we discussed in Section III, this data is provisional and will change as records are added/amended.

Exhibit 17 includes demographic information for the 15,978 registered deaths from COVID-19.

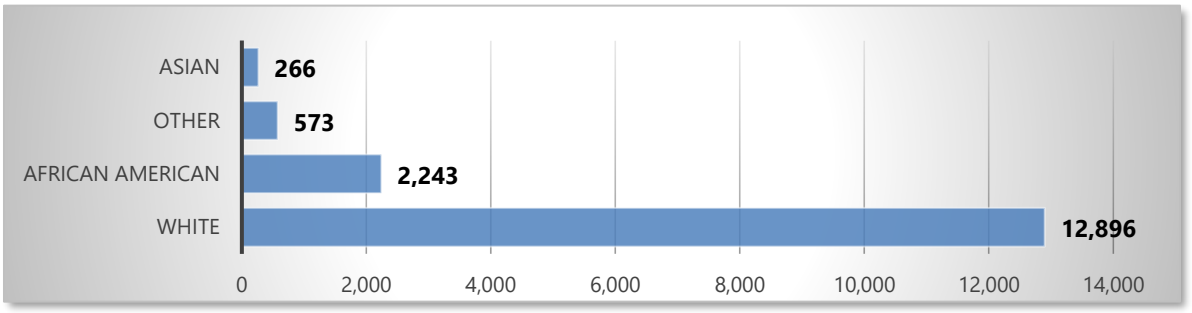
Exhibit 17

Demographic Detail on COVID-19 Deaths*
(CY 2020)
n = 15,978

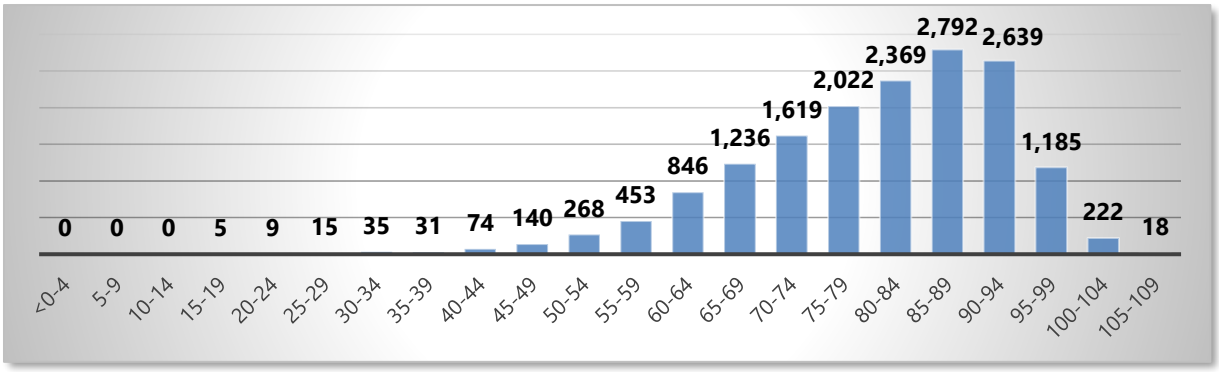
Gender



Race



Age



Note: */Information is reproduced from DOH Weekly Report of COVID-19 Deaths, December 31, 2020. These deaths are as of 11:59 p.m. on December 30, 2020 and differs from other totals reported because of when the deaths were registered.
Source: Developed by LBFC staff from information provided by DOH.

The previous exhibit is based on raw data counts and does not factor for deaths based on percentage of the population. Interestingly, the deaths are evenly split by gender, with women accounting for a slightly larger margin of the deaths (50.6 percent) than men (49.4 percent). There are also many more deaths among whites, than other races (again, not factoring percentage of the population). Perhaps most significant though is the age of those who have died, and in particular, the elderly population. Nearly 58 percent of all deaths were aged 80 and older, with the largest number of deaths (2,792) occurring among those 85-89. This fact is especially important because the elderly population is also likely to have several comorbidities or other contributing conditions.

On the issue of comorbidities, we used limited data from the Weekly Report to categorize comorbidities. DOH reported that of the 15,978 registered deaths 63 percent of the registered deaths included comorbidities, and 37 percent did not include comorbidity data. As we explained in Section III, comorbidity is listed in Part II of the death record and includes all conditions that contributed but did not cause death. As such, there can be multiple conditions listed that are related or unrelated to one another (but contributed to the death). For example, an elderly decedent might have had dementia (a neurological condition) and diabetes (a metabolic condition) listed as comorbidities. In this example, the two conditions are unrelated, but contributed to the person's death and so each would be counted as contributing to the death.

DOH tracks comorbidities by eight classifications, as follows:

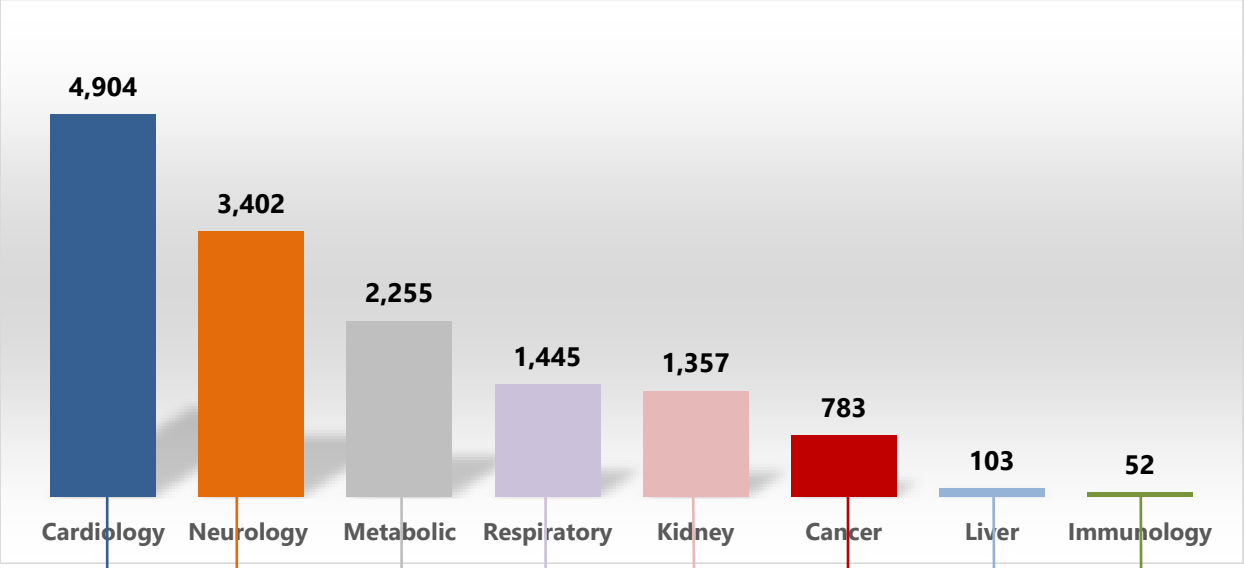
1. Cardiology.
2. Neurology.
3. Respiratory.
4. Metabolic.
5. Liver.
6. Kidney.
7. Cancer.
8. Immunology.

Within each of these classifications, sub-classifications may also be tracked. For example, within the cardiology classification are congestive heart failure, coronary artery disease, and hypertension. There is no sub-classification for "cancer." Exhibit 18 lists these classifications and provides additional information on any sub-classifications for comorbidities.

Exhibit 18

Comorbidity and COVID-19 Deaths*
(By Classification and Detail)

Classification



Detail

Sub-comorbidities	Count	Sub-comorbidities	Count
Hypertension	2,624	Chronic Kidney Conditions	1,072
Coronary Artery Disease	1,201	End Stage Renal Failure	285
Congestive Heart Failure	1,079	Cancer (All)	**783**
Dementia	3,046	Cirrhosis	87
Parkinson's	356	Chronic Liver Conditions	16
Diabetes	1,876	Organ Transplant	33
Obesity	379	HIV	19
COPD	1,201		
Sleep Apnea	124		
Asthma	120		

Note: */Information is reproduced from DOH Weekly Report of COVID-19 Deaths, December 31, 2020. Includes only comorbidities currently being tracked by DOH.

Source: Developed by LBFC staff from information provided by DOH.

As depicted above, with more than 4,900 occurrences, cardiology is the largest grouping of comorbidities among COVID-19 deaths. However, within the sub-comorbidity classifications, dementia, a neurological disorder of the brain, is the leading comorbidity listed on death records. Dementia primarily afflicts the elderly. As we noted, most of the deaths

in Pennsylvania (58 percent) from COVID-19 were among those 80 and older. As a result, the high occurrence of this condition links to the fact that most deaths have occurred among the elderly. However, as noted by DOH, the subset of comorbidities should not be interpreted as a list of conditions that caused an individual to be more susceptible to the disease.

Difference Between DOH Classifications and CDC/NCHS Classifications

Thus far, we have presented information on the breakout of the 17,834 COVID-19 deaths that DOH has classified, and further provided limited detail about 15,978 of those deaths from DOH's Weekly Report. The final piece of this discussion area is a review of the difference between how DOH reported these 17,834 deaths, and how the CDC/NCHS coded the actual underlying causes—and how that issue involved our need to issue a scope limitation.

As noted earlier, DOH supplied us with a data file containing 17,834 records, which represented deaths attributed to COVID-19 that occurred during CY 2020 and that had been registered and/or amended through March 18, 2021. This data file contained three fields: (1) the record number, (2) DOH's internal classification of the death, and (3) the CDC/NCHS' final coding of the underlying cause of death.

There is an important distinction between these last two fields. **DOH's internal classifications are determined from review of all of Part I and all of Part II. Conversely, the CDC/NCHS coding is only the underlying cause of death, as reported on the lowest line of Part I.** The distinction between what DOH provided to us in these fields can be confusing; thus, an analogy may provide better context. Consider the following:

> For a recent major league baseball game (e.g., Phillies or Pirates) a researcher wants to know two aspects about that game: (1) the overall attendance, and (2) the attendance of those who are fans of the home team. Further complicating this task is that the researcher cannot ask the ticketholder which team they support.
>
> Determining overall attendance would be relatively easy. The researcher could simply count the total ticket receipts for that day. However, determining the second aspect would be more difficult. For this aspect, the researcher could review total ticket receipts initially, but because he/she cannot speak to the ticketholder, other

> indicators of team support would be needed. For example, the researcher might review ticketholders as they entered the stadium to determine: How many ticketholders were wearing jerseys or had other merchandise of the home team? Additionally, the researcher might try to gauge fan attendance by crowd noise. For example, if the home team scored a run, approximately how many of the ticketholders cheered—and conversely—if the visiting team scored, how many ticketholders cheered?

Although the above is a simplistic example, we face similar problems with the data presented to us. One key problem we have is that the data is entirely self-reported. While we believe the data to be reasonably accurate, we have no bases for testing it—and what sources we might use as corroborating evidence (i.e., primarily the weekly report) is also self-reported. Using the analogy above, this problem is like reading a press release about the game's attendance (i.e., it is believed to be true, but there is no confirmation).

Another problem presents itself when we try to determine the accuracy of the records that were provided to us. Here again, this problem becomes circular and becomes a bit like comparing apples and oranges—both are fruit, but different. If we use the CDC/NCHS' coding as the basis for determining whether DOH was correct in classifying the death as COVID-19, that only tells part of the story because the CDC/NCHS data only reflects information reported in Part I.

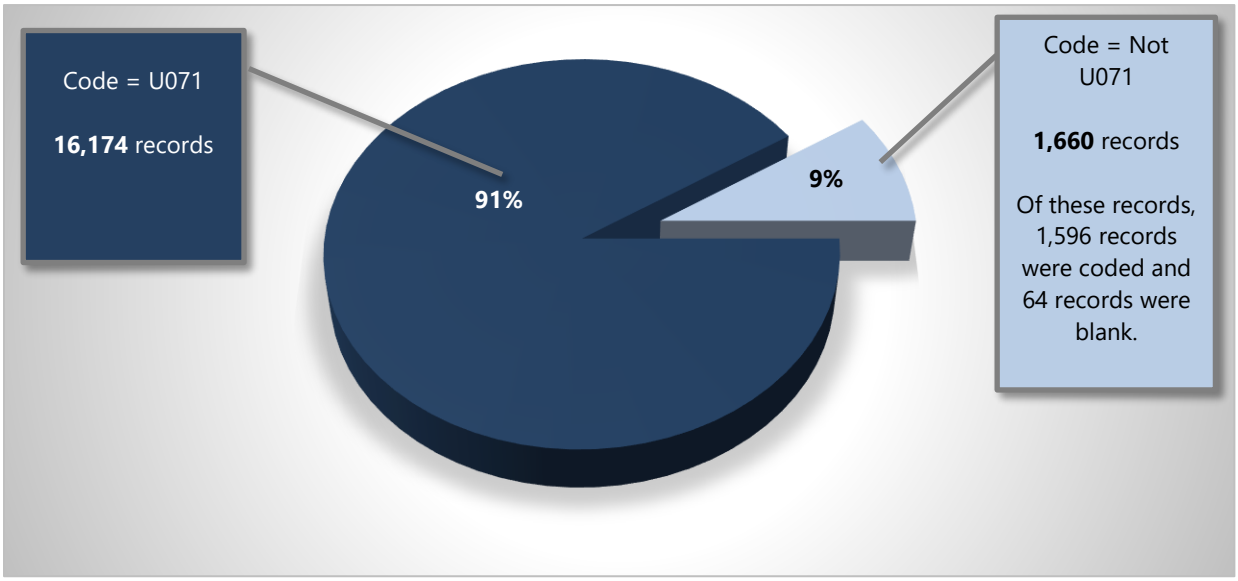
One can see the problem in trying to compare these sources for authenticity and accuracy. On the one hand, DOH is using a more broad-based process (Part I and Part II), which is accurate for disease surveillance purposes—but on the other hand—the data supplied to us from the CDC/NCHS is a more refined review using only Part I (and providing a code for the underlying cause of death). Neither approach is incorrect, but each will have different results.

Circling back to the baseball analogy, DOH is counting all ticketholders as fans, whereas the CDC/NCH is performing its procedures to determine whether the ticketholder is a fan or non-fan. In the end, while the attendees are all ticketholders, not all are home team fans. Similarly, we assume that all the provided records are COVID-19 deaths, but perhaps not all had an underlying cause of death as COVID-19 (and as discussed later, some did not).

We were able to accomplish some of this analysis with the data provided to us. First, assuming that all 17,834 records represent COVID-19 deaths, we then matched the ICD-10 coding. For example, where the deaths had a code of "U07.1" (the ICD-10 code used for COVID-19),[60] we could assume there was agreement between DOH and the CDC/NCHS that the death had an underlying cause of COVID-19 (e.g., a "ticketholder" and a "fan"). Where the two fields differed, either the death was likely internally classified by DOH as a COVID-19 death using information from Part II of the death certificate/record, or the death was not COVID-19-related (e.g., non-fan).[61] Our results are presented in Exhibit 19.

Exhibit 19

Comparison of DOH Internal Classifications to CDC/NCHS Coding for UCOD
(CY 2020)
n = 17,834 deaths



Source: Developed by LBFC staff from information provided by DOH.

[60] Recall from Section III that ICD-10 coding for COVID-19 could be either U071.1 (laboratory confirmed) or U701.2 (probable). However, the CDC/NCHS only uses U071.1 for mortality purposes (reported as just U071). Therefore, while some COVID-19 deaths may be probable because the CDC/NCHS lacks access to testing results, it assigns the U071.1 code to those deaths. In all records we received from DOH, only U071 was reported for COVID-19.

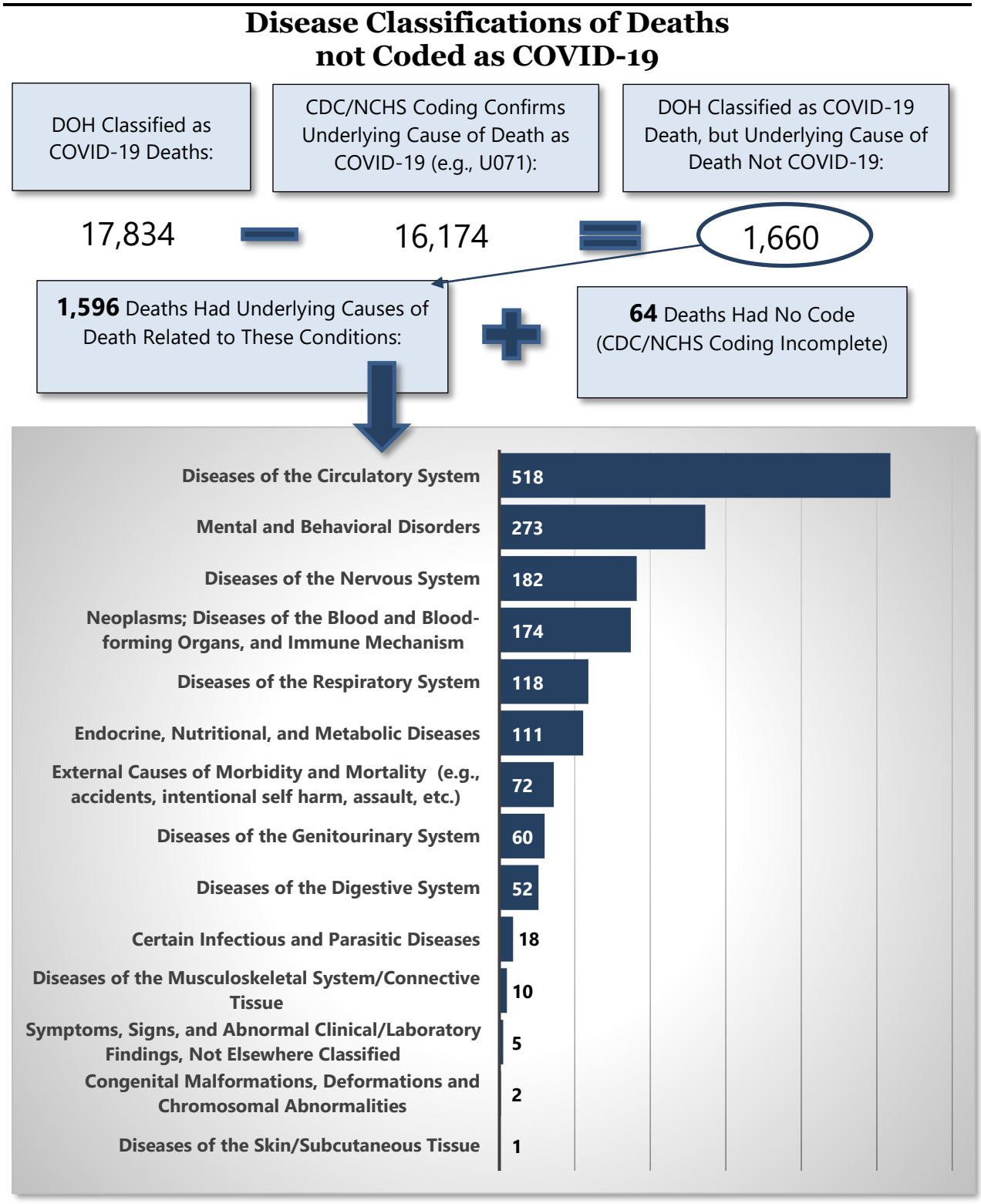
[61] DOH noted that it was also possible that the cause of death was originally filed without listing COVID-19 as the UCOD, and then after receiving the UCOD coding back from CDC/NCHS, the death record could have been amended and DOH is awaiting the updated UCOD from CDC/NCHS. Additionally, DOH could challenge the original code applied to the UCOD and is awaiting a manual reanalysis by CDC/NCHS (and updated coding if CDC/NCHS agree to the change of the UCOD). We do not know the frequency of these cases. We originally asked for the number of records that had been amended, but DOH stated it was unable to comply with the request because of the time and resources needed to review the records.

As shown in the previous exhibit, 16,174 records, or 91 percent of all records, had a DOH designation as a COVID-19 death and had an underlying cause of death as COVID-19. Of the remaining 1,660 records not coded as COVID-19 (U071), 64 were blank (0.4 percent), which simply means that the CDC/NCHS had not completed its review and coding for the record. More significantly, however, 1,596 records (8.9 percent) had an underlying cause of death as not COVID-19. Referring to our previous discussion, this occurrence likely means that COVID-19 contributed to the death, but the deaths did not have COVID-19 as an underlying cause of death. This distinction is a matter of semantics, because in the tabulation (and per the CDC/NCHS guidance) DOH counts these deaths as "COVID-19 deaths."

These 1,596 deaths are of interest to us. However, without access to the underlying death record, we know nothing more about the death other than the fact that the underlying cause of death was something other than COVID-19. As stated above, it is likely that DOH used information from Part II of the death certificate to make its determination that the death was a COVID-19 death. This aspect is something we would have verified, if granted access to the records.

Despite the limitations imposed upon us by DOH, as part of our review we further investigated the ICD-10 coding for each of these 1,596 records. We then linked the deaths to various disease, disorders, and causes based on the assigned code. Exhibit 20 reveals the results of this research:

Exhibit 20



Source: Developed by LBFC staff from information provided by DOH.

As shown above, disease of the circulatory system was the leading category of non-COVID underlying causes of death. Interestingly, the second highest classification was mental and behavioral health disorders. Given that this classification seems unrelated to the sequence of death typically initiated by COVID-19, we assume that COVID-19 was listed as a comorbidity by the medical certifier. Here again, we would be interested in learning more about these deaths and the other "exceptions," as it would allow us to determine the frequency by COVID-19 deaths are being properly, accurately, and consistently reported to DOH.

In the end, we are not disputing that under CDC/NCHS' guidance these 1,596 deaths (representing approximately 9 percent of all COVID-19 deaths) may be related to COVID-19. However, we believe it is important to distinguish these deaths as either being from Part I or Part II of the death certificate and not leaving the public or other users to guess. We plan to revisit this issue, as well as our access to records, in future reports.

RECOMMENDATIONS

1. **The General Assembly should consider amending the Vital Statistics Law to expressly grant access to the records to legislative agencies**. To avoid any future confusion, the General Assembly should amend the Vital Statistics Law to expressly grant legislative service agencies access to all vital record information as needed to conduct authorized research and studies.

Appendix A - House Resolution 1087 of 2020

PRIOR PRINTER'S NO. 4602 PRINTER'S NO. 4624

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE RESOLUTION

No. 1087 Session of 2020

INTRODUCED BY KLUNK, BARRAR, ECKER, FEE, KAUFFMAN, MOUL, ROTHMAN, RYAN, COX, GAYDOS, OWLETT, CAUSER, SAYLOR, OBERLANDER, HICKERNELL, HERSHEY, JONES AND TOEPEL, NOVEMBER 12, 2020

AS AMENDED, HOUSE OF REPRESENTATIVES, NOVEMBER 19, 2020

A RESOLUTION

Directing the Legislative Budget and Finance Committee to conduct ~~an audit~~ A REVIEW of the data collection ~~systems utilized~~ by the Department of Health during the COVID-19 pandemic. <--

WHEREAS, The novel coronavirus was first discovered in Wuhan, China, at the end of December of 2019; and

WHEREAS, The novel coronavirus is the virus that causes COVID-19; and

WHEREAS, The first documented case of COVID-19 appeared in this Commonwealth in March of 2020; and

WHEREAS, On March 6, 2020, Governor Wolf signed a declaration of disaster emergency to mitigate the spread of COVID-19 in this Commonwealth; and

WHEREAS, The Secretary of Health has served as the primary point of contact for all COVID-19 infection data in this Commonwealth through her role as the head of the Department of Health in accordance with the Disease Prevention and Control Act of 1955; and

WHEREAS, The collecting and sharing of information with respect to COVID-19 infection rates, locations of positive COVID-19 cases, mortality data and other information within the purview of the Department of Health is vital to contain the virus and inform the public; and

WHEREAS, The Bureau of Health Statistics and Registries of the Department of Health is responsible for the death certificates of all individuals who have died in this Commonwealth, including individuals who have died for reasons other than COVID-19; and

WHEREAS, The coroners and medical examiners in this Commonwealth are responsible for investigating deaths that occur in this Commonwealth due to a communicable disease; and

WHEREAS, In late April of 2020, the Pennsylvania State Coroners Association publicly stated that there was a conflict between the number of COVID-19 deaths reported by the Department of Health and the number of COVID-19 deaths reported by coroners in this Commonwealth; and

WHEREAS, Due to the alarming conflict in the number of COVID-19 deaths reported by the Department of Health and coroners in this Commonwealth, the Department of Health removed hundreds of deceased individuals from the Department of Health's list of COVID-19 deaths without an explanation or a review of the death certificates for the removed individuals; and

WHEREAS, On May 26, 2020, the Department of Health released a report specifying the number of COVID-19 cases discovered in nursing homes; and

WHEREAS, Upon the release of the Department of Health's report, nursing homes immediately contested the information in the report, including information in the report stating that

COVID-19 cases exceeded the number of beds in certain nursing homes; and

WHEREAS, More than seven months since the beginning of the COVID-19 pandemic, there is still no consistent reporting mechanism for COVID-19 cases and deaths in nursing homes; and

WHEREAS, Despite nursing homes and other long-term care facilities providing numerous reports on COVID-19 to the Department of Health and the Department of Human Services, information on COVID-19 for nursing homes and other long-term care facilities is often delayed more than a week and the information often includes many missing details; and

WHEREAS, On May 22, 2020, the Department of Health announced that the Department of Health was combining COVID-19 testing results from viral tests and antibody tests; and

WHEREAS, A viral or polymerase chain test reaction test is utilized to determine if a patient has a current viral infection of COVID-19; and

WHEREAS, An antibody test is utilized to determine if a patient had a prior or previously undiagnosed or asymptomatic viral infection of COVID-19; and

WHEREAS, The Department of Health's decision to combine the two different COVID-19 test results when submitting reports on COVID-19 to the Centers for Disease Control and Prevention results in an over inflation of the status of COVID-19 cases in this Commonwealth; and

WHEREAS, The Department of Health continues to report COVID-19 data on polymerase chain test results that is more than 30 days old; and

WHEREAS, In addition to the Department of Health's decision to combine the polymerase chain test results for COVID-19 and

the antibody test results for COVID-19 when submitting reports on COVID-19 to the Centers for Disease Control and Prevention, the Department of Health's failure to SEPARATELY report antibody <-- testing to the Centers for Disease Control and Prevention has distorted the status of COVID-19 cases in this Commonwealth; and

WHEREAS, Residents of this Commonwealth have logged numerous complaints about the causes of death listed on the death certificates of loved ones; and

WHEREAS, Death certificates in this Commonwealth can be filed by coroners, medical examiners, treating health care providers and other authorized individuals; and

WHEREAS, A review of the death certificate information from other states shows numerous inaccuracies in the reporting of COVID-19 deaths and the comorbidities associated with the deaths; and

WHEREAS, During two days in June of 2020, this Commonwealth recorded a 100% positive rate for COVID-19 on all tests performed; and

WHEREAS, Despite this statistical anomaly, the Department of Health has not initiated or reviewed the COVID-19 data reported on those two days to review necessary changes to data reporting; and

WHEREAS, From October 20 to October 21, 2020, the COVID-19 data provided by the Department of Health showed more COVID-19 deaths in long-term care facilities than in this entire Commonwealth; and

WHEREAS, This higher COVID-19 death rate data in long-term care facilities is a statistical impossibility; and

WHEREAS, Instances of anomalies, inaccuracies, statistical impossibilities and other reporting concerns are still happening

at the Department of Health more than seven months after the beginning of the COVID-19 pandemic; and

WHEREAS, Residents of this Commonwealth need to have accurate and reliable COVID-19 data to make choices for their health, safety and security; therefore be it

RESOLVED, That the House of Representatives direct the Legislative Budget and Finance Committee to conduct ~~an audit~~ A <-- REVIEW of the data collection ~~systems utilized~~ by the Department <-- of Health during the COVID-19 pandemic; and be it further

~~RESOLVED, That the Legislative Budget and Finance Committee~~ <-- ~~review information received from nursing homes, long-term care facilities, health care facilities, coroners and medical examiners to determine the accurate number of COVID-19 cases in this Commonwealth; and be it further~~

~~RESOLVED, That the Legislative Budget and Finance Committee's audit include all of the following information:~~

~~(1) An analysis of the daily total COVID-19 reports submitted to the Department of Health.~~

~~(2) An analysis of the daily total COVID-19 reports received by the Department of Health by other State agencies.~~

~~(3) An analysis of the COVID-19 reports provided by county coroners, medical examiners and local boards of health.~~

~~(4) An analysis of the changes in the daily total COVID-19 reports provided by the Department of Health, including the revised numbers of COVID-19 positive test results and decreases to the total number of reported cases.~~

~~(5) An analysis of the comorbidities reported by patients who tested positive for COVID-19 in addition to the positive viral diagnoses.~~

~~(6) Conclusions regarding the areas where data discrepancies have been found and how the discrepancies can be avoided in future;~~

~~and be it further~~

~~RESOLVED, That the Legislative Budget and Finance Committee review the death certificates of deceased individuals which have been labeled as COVID 19 deaths and analyze the following information:~~

~~(1) The location of death.~~

~~(2) The individual who recorded the death.~~

~~(3) The method of recording the chain of events regarding the death.~~

~~(4) The location of COVID 19 in the chain of events listed as the cause of death;~~

~~and be it further~~

~~RESOLVED, That the Legislative Budget and Finance Committee review the reporting of COVID-19 data to determine the number of viral tests and antibody tests performed in this Commonwealth, including the following information:~~

~~(1) The number of polymerase chain test reaction tests performed, including the number of samples tested and the number of individuals tested.~~

~~(2) The number of COVID-19 positive polymerase chain test reaction results, including the number of times the same individual tested positive for COVID-19.~~

~~(3) The number of COVID-19 negative polymerase chain test reaction results, including the number of times the same individual tested negative for COVID-19.~~

~~(4) The number of antibody tests or other serum tests performed, including the number of samples tested and the~~

~~number of individuals tested.~~

~~(5) The number of COVID-19 positive antibody tests or other serum tests performed, including the number of times the same individual tested positive for COVID-19.~~

~~(6) The number of COVID-19 negative antibody tests or serum tests performed, including the number of times the same individual tested negative for COVID-19.~~

~~(7) A determination on when the Department of Health ceased combining COVID-19 testing results from viral tests and antibody tests when submitting reports on COVID-19 to the Centers for Disease Control and Prevention.~~

~~(8) A determination on how other COVID-19 test results are collated, counted and reported in this Commonwealth;~~

~~and be it further~~

~~RESOLVED, That the Legislative Budget and Finance Committee review the anomalies in the reporting of COVID-19 data by the Department of Health, including, but not limited to, all of the following:~~

~~(1) The dates when the positivity rate of COVID-19 tests in this Commonwealth was more than 50%.~~

~~(2) The laboratories that performed the COVID-19 tests described under paragraph (1).~~

~~(3) The brands of the COVID-19 tests described under paragraph (1).~~

~~(4) The types of the COVID-19 tests described under paragraph (1).~~

~~(5) The counties where the COVID-19 tests described under paragraph (1) were performed and the number of COVID-19 tests that were performed on different dates than the COVID-19 tests described under paragraph (1);~~

~~and be it further~~

~~RESOLVED, That the Legislative Budget and Finance Committee review the delays in reporting of positive COVID-19 cases and the circumstances that are leading to delays in excess of 40 days in the reporting of positive COVID-19 cases; and be it further~~

RESOLVED, THAT THE LEGISLATIVE BUDGET AND FINANCE COMMITTEE <-- REVIEW DATA COLLECTED AND DISSEMINATED BY THE DEPARTMENT OF HEALTH AND ISSUE A REPORT OF ITS FINDINGS; AND BE IT FURTHER

RESOLVED, THAT THE REPORT INCLUDE, BUT NOT BE LIMITED TO, A REVIEW OF ALL OF THE FOLLOWING:

(1) THE NUMBER AND TYPE OF COVID-19 TESTS COMPLETED IN THIS COMMONWEALTH, INCLUDING A REVIEW OF ALL OF THE FOLLOWING:

(I) INFORMATION ON THE COMMINGLING OF TEST RESULTS FOR POLYMERASE CHAIN REACTION TESTS AND ANTIBODY TESTS.

(II) THE DATA SYSTEM USED TO ENSURE COVID-19 POSITIVE TESTS FROM THE SAME INDIVIDUAL WERE NOT REPORTED AS MULTIPLE POSITIVE CASES.

(III) THE TYPE OF COVID-19 TESTS COMPLETED, INCLUDING POLYMERASE CHAIN REACTION TESTS, ANTIBODY TESTS AND RAPID ANTIGEN TESTS.

(2) THE POLICIES, PROCEDURES AND PRACTICES OF STATE AGENCIES REPORTING COVID-19 TEST RESULTS TO THE DEPARTMENT OF HEALTH AND THE CENTERS FOR DISEASE CONTROL AND PREVENTION, INCLUDING A REVIEW OF ALL OF THE FOLLOWING:

(I) THE COVID-19 REPORTING REQUIREMENTS OF STATE AGENCIES, HEALTH CARE FACILITIES AND OTHER LONG-TERM CARE FACILITIES TO DETERMINE IF DUPLICATION OF REPORTING THROUGH MULTIPLE DATA SYSTEMS HAS RESULTED IN MORE

ACCURATE DATA OR A DUPLICATION OF INFORMATION.

(II) LABORATORY REPORTING FOR COVID-19 TO THE DEPARTMENT OF HEALTH TO DETERMINE WHY THERE ARE DELAYS IN REPORTING COVID-19 INFORMATION TO DEPARTMENT OF HEALTH OR BY THE DEPARTMENT OF HEALTH THAT HAS RESULTED IN DELAYS OF INFORMATION BEING REPORTED ON THE DEPARTMENT OF HEALTH'S COVID-19 DASHBOARD.

(III) THE PROCEDURES UTILIZED BY THE DEPARTMENT OF HEALTH TO REVISE POSITIVE COVID-19 TEST RESULTS AND COVID-19 DEATHS IN DAILY REPORTING OR ON THE DEPARTMENT OF HEALTH'S COVID-19 DASHBOARD.

(3) THE DEATH CERTIFICATES FOR RESIDENTS OF THIS COMMONWEALTH WHO MAY HAVE DIED FROM COVID-19 TO ENSURE THE DEATHS WERE PROPERLY, ACCURATELY AND CONSISTENTLY REPORTED TO DEPARTMENT OF HEALTH;

AND BE IT FURTHER

RESOLVED, THAT THE LEGISLATIVE BUDGET AND FINANCE COMMITTEE INCLUDE ANY ADDITIONAL INFORMATION IN ITS REPORT AS DEEMED NECESSARY TO EFFECTUATE THE PURPOSES OF THIS RESOLUTION; AND BE IT FURTHER

RESOLVED, That the Legislative Budget and Finance Committee issue a report on the COVID-19 data collected by the Department of Health for the period beginning March 6, 2020, and ending March 6, 2021, or for the period beginning March 6, 2020, and ending ~~60~~ 90 days after expiration or termination of the Governor's declaration of disaster emergency issued on March 6, 2020, whichever is later; and be it further <--

RESOLVED, That the Legislative Budget and Finance Committee issue interim reports every ~~60~~ 90 days beginning 90 days after the adoption of this resolution on the COVID-19 information <--

collected and any interim findings.

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Appendix B - DOH Letter Denying LBFC Access to Records

COMMONWEALTH OF PENNSYLVANIA
GOVERNOR'S OFFICE OF GENERAL COUNSEL

March 1, 2021

Patricia A. Berger, J.D.
Executive Director
Legislative Budget and Finance Committee
Room 400 Finance Building
P.O. Box 8737
Harrisburg, PA 17105-8737

pberger@palbfc.us

Re: HR 1087 – LBFC Engagement Letter

Dear Ms. Berger:

The Pennsylvania Department of Health (Department) has been meeting productively with staff from the Legislative Budget and Finance Committee (LBFC) to provide information for a report, which the committee is compiling under House Resolution 1087 of 2020. Most recently, LBFC has requested the Department provide 100 death certificates selected by LBFC for persons whose deaths are attributable to COVID-19, with redactions of certain personally identifiable information. This request was made to the Department as the custodian of the Commonwealth's vital statistics records under the Vital Statistics Law of 1953 (VSL), 35 P.S. §§ 450.101-450.1003. The Department has carefully analyzed LBFC's request and its ability to provide the death certificates within the constraints of the VSL and has determined that the Department may not provide the death certificates to LBFC as requested.

The Department is prohibited from issuing or disclosing any vital statistics record, including a death certificate, in part or in whole, except in accordance with the VSL. 35 P.S. § 450.801. Sections 804, 805, and 806 of the VSL, respectively, provide for three statutory exceptions to this prohibition: (1) disclosure to a person with a direct interest for the determination of a personal or property right; (2) disclosure for research; and (3) disclosure to federal, state or municipal agencies of government conducting an official duty. 35 P.S. §§ 450.804, 450.805, and 450.806. The Department analyzed[1] each of these exceptions, including the exception provided

[1] Section 804 of the VSL requires disclosure of vital statistics records or parts of vital statistics records if the Department has determined that the person seeking access to the record has a direct interest in its contents and that the information contained in the record is necessary for the

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pennsylvania
DEPARTMENT OF HEALTH

for under Section 806 of the VSL, as the LBFC stated it is an agency of the General Assembly in its request.[2]

For the LBFC to receive death certificates under Section 806 of the VSL, the Department is required to determine that LBFC is a federal, state, or municipal *agency of government* and is conducting an official duty. The VSL does not define an "agency of government," so, in accordance with Section 1903 of the Statutory Construction Act, the term must be construed according to its common and approved usage. Although the term "agency of government" no longer appears in statute, it has been replaced with the succinct term "government agency." The definition of "government agency" is generally consistent across Commonwealth statutes and includes executive agencies and local government; specifically, "Commonwealth agency," "political subdivision," and "municipal or other local authority." *See* 23 Pa.C.S. § 4302; 42 Pa.C.S. § 102; 62 Pa.C.S. § 3102; and 74 Pa.C.S. § 1701.

Importantly, none of these definitions of "government agency" includes the General Assembly or the language legislature or its agencies.[3] For this reason, the Department cannot conclude that LBFC would be included in the common and approved usage of "agency of government" under the VSL. Therefore, the Department cannot disclose the death certificates as requested to LBFC.

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determination of a personal or property right. 35 P.S. § 450.804. As a bipartisan, bicameral committee created by statute to "study… the revenues, expenditures and fiscal problems of the Commonwealth", the LBFC does not have any direct interest in the content of any vital record to determine its personal or property interests. 46 P.S. § 70.2. As such, this exception does not apply to the LBFC.

Section 805 of the VSL allows the Department to permit the use of vital statistics records for research, subject to the strict supervision by the Department to ensure the use of the records is limited to research purposes. 35 P.S. § 450.805. However, as stated previously, the LBFC is a statutorily-established entity that studies the revenues, expenditures of the Commonwealth and fiscal information concerning the budget. It is not an entity established for the purpose of conducting research relating to vital statistics records or causes or manners of death. As such, this exception does not apply to the LBFC.

[2] The LBFC's request, provides, in part, the following:

"*We recognize that death records are not a public record; however, it is also important to underscore the fact that the Legislative Budget and Finance Committee is an agency of the General Assembly with broad access to agency records. As I mentioned, LBFC workpapers are not public records and are not subject to "Right to Know Law" requirements.*"

[3] *See also* Logan Greens Cmty. Ass'n, Inc. v. Church Reserve, LLC, 1819 C.D. 2012, 2013 WL 5302578, at *3 (Pa.Cmwlth. Sept. 20, 2013) (General Assembly not a "government agency" when determining whether a portion of the Planned Community Act amounted to a government agency decision under the Permit Extension Act).

Further, even if the Department were able to conclude LBFC was an "agency of government", it must also conclude that LBFC's request is in the interest of conduct of an "official duty." As defined by law, LBFC's official duties are as follows:

> (1) The committee shall have power to request, receive, review, examine, study, ascertain and compare fiscal information concerning the budget, the revenues and expenditures of the Commonwealth and to make recommendations to the Legislature, when found advisable, directed to the elimination of unnecessary expenditures and to the promotion of economy in the government of the Commonwealth.
>
> (2) To make current examination and, when pertinent, reports concerning the current condition of all State funds, appropriations and other moneys, whether or not such appropriations are being currently expended for the purposes and within the statutory restrictions provided by the Legislature, and concerning the current availability of revenue to meet expenditures under appropriations.
>
> 46 P.S. § 70.3 (relating to powers and duties of committee).

After review of these statutorily-prescribed duties at 46 P.S. § 70.3, the Department cannot reach the conclusion that the release of these records is related to the LBFC's statutorily-prescribed duties. Specifically, the Department has determined that the death certificates sought by LBFC are not related to any fiscal information concerning the budget, revenues or expenditures of the Commonwealth and do not pertain to the condition of State funds, appropriations, or other moneys. Further, although the LBFC is directed via a House resolution to create a report regarding the reporting of death records, this single chamber resolution does not supersede the restrictions under the Vital Statistics Law. Specifically, one chamber of the General Assembly cannot expand the statutory scope of authority of any entity unilaterally. Pa. Const. art. III, § 1.[4]

For these reasons, the Department has concluded that disclosure of 100 death certificates of persons whose deaths are attributable to COVID-19 as requested by LBFC does not fall within any statutory exceptions of the VSL and, therefore, the disclosure is prohibited by law. The Department appreciates the consideration and professionalism of the LBFC to date. However, the Department is prohibited from disclosing vital statistics records in accordance with law.

The Department will continue to cooperate with LBFC, including examining alternative data or reports that may allow LBFC to meet its objectives, but such cooperation is required to stay within the statutorily-defined limits of the Department's authority, including the requirement to limit disclosure of certain records.

---

[4] PA. CONST. Art. III, § 1§ 1. Passage of laws.
No law shall be passed except by bill, and no bill shall be so altered or amended, on its passage through either House, as to change its original purpose.

Thank you for your understanding of the Department's position on this matter and please do not hesitate to contact me if you have any questions.

Sincerely,

Yvette M. Kostelac

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Date: 2021.03.01 10:13:35 -05'00'

Yvette M. Kostelac
Chief Counsel

cc: Meghna Patel, Deputy Secretary for Health Innovation
Peter Blank, Director of Policy
Audrey Marrocco, Director, Bureau of Health Statistics and Registries
Jennifer G. Whare, Deputy General Counsel
Sarah Kurish, Assistant Counsel

Appendix C - LBFC Counsel's Response to DOH

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A JOINT COMMITTEE OF THE PENNSYLVANIA GENERAL ASSEMBLY

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March 15, 2021

Yvette M. Kostelac
Chief Counsel
Governor's Office of General Counsel
Office of Legal Counsel
Department of Health
625 Forster Street
Harrisburg, PA 17120-0701

Re: HR 1087

Dear Ms. Kostelac:

I have reviewed your letter of March 1, 2021, in which you have denied Legislative Budget and Finance Committee (LBFC) staff access to Pennsylvania death certificates, even under strict supervision by the Department of Health (DOH) and with personally identifiable information redacted. The Vital Statistics Law (VSL) at Sections 805 and 806, generally allows for access of vital records by state agencies conducting official duties and also allows access for research, such as the LBFC's study relating to HR 1087. LBFC access of information contained in death records is clearly permissible under Sections 805 and 806 of the VSL. I respectfully ask that you reconsider your decision.

You stated in your letter the LBFC may not access death certificates under the VSL because of the following:

- The LBFC is not an "agency of government" under Section 806 of the VSL.
- The LBFC's work is not "in the interest of conduct of official duty" under Section 806 of the VSL.
- The LBFC's work in studying and analyzing the reporting of death records in the Commonwealth does not constitute "research" under Section 805 of the VSL because the LBFC is not an entity "established for the purpose of conducting research relating to vital statistics records or causes or manners of death".

While the LBFC staff recognizes the custodial duties placed upon DOH to preserve and protect vital records, your conclusions above appear to exceed the scope of DOH's custodial duties and obstruct the permitted access intended under Sections 805 and 806 of the VSL based on the language used in those provisions.

I. Agency of the Government

The LBFC is a bipartisan, bicameral legislative service agency, consisting of twelve members of the General Assembly. The LBFC was created by Act 195 of 1959, and as such, it is clearly an agency of the government. You are correct that the VSL does not define these terms but I disagree that a simple replacement of the terms with the different term "government agency" is warranted, and I also

disagree that in reviewing statutory law, there is an obvious and necessary conclusion that an "agency of government" consistently excludes legislative agencies.

You point to 23 Pa CS 4302 (relating to Domestic Relations), 42 Pa CS 102 (relating to Judicial Procedure), 62 Pa CS 3102 (the Procurement Code), and 74 Pa CS 1701 (from the Metropolitan Transportation Authority's Law). From that representative sampling of statutory references, you conclude the definition of "government agency" across Pennsylvania statutes consistently does not include legislative agencies. A closer review of state statutes, however, including the four you cited, shows that Pennsylvania statutory terms for "agency" or "government" or "government agency" do not consistently exclude the legislature. To the contrary these terms in state statutes show that: 1) they include "any agency of the Commonwealth", and 2) they show that when the legislature is intended to be excluded, there is express language to that effect. Your cites to Title 23, Title 42, and Title 62 confirm this by defining a government agency as "any agency of the Commonwealth." Title 42 then defines the government to include the legislature. Specifically, Title 42 defines "Commonwealth government" as:

> The government of the Commonwealth, including the courts and other officers or agencies of the unified judicial system, the General Assembly and its officers and agencies, the Governor, and the departments, boards, commissions, authorities and officers and agencies of the Commonwealth, but the term does not include any political subdivision, municipal or other local authority, or any officer or agency of any such political subdivision or local authority. [Emphasis added]

The Procurement Code (Title 62), which you also cite, further clarifies the concept of "Commonwealth agency" by distinguishing between an executive agency and an independent agency (and state-affiliated agency). An executive agency is under the Governor's jurisdiction and an independent agency is not. In doing so, legislative agencies are expressly excluded from Procurement Code coverage. The need to carve out legislative agencies from the statutory definitions of "agency" shows that without the express carveout, legislative agencies would be included [1] Note that neither Titles 23 nor 42 expressly excludes the legislature from "an agency of the Commonwealth". Similarly, the VSL uses the two terms "agency" and "government" but does not use any express language that excludes legislative agencies.

Moreover, looking beyond the four statutes you have cited, we see that definitions of "government" in Pennsylvania statutes many times include the legislature. For example, the Administrative Code defines "government unit" as "The General Assembly and its officers and agencies, any government agency or any court or other officer or agency of the unified judicial system." The Right-to-Know Law defines "agency" as a "Commonwealth, local, judicial, or legislative agency." And Pennsylvania's Sunshine Act defines an "agency" as "[t]he body, and all committees thereof authorized by the body to take official action or render advice on matters of agency business, of all the following: the General Assembly, the executive branch of the government of this Commonwealth, …." [Emphasis added in all]. Obviously, absent express language to the contrary excluding the legislature, the words "agency of the government", as are used in the VSL, must be read to include legislative agencies. Therefore, the LBFC may access death records as an agency of the government under VSL Section 806.

II. Official duty

You also conclude, however, that the LBFC is not conducting any "official duty" in seeking access to death certificates, thus providing DOH a second reason to deny LBFC access under Section 806. Your rationale focuses on the LBFC's authority under 46 P.S. 70.3 to review fiscal information and the condition of state funds, etc. You overlook, however, the broader language under 46 P.S 70.2 that clearly grants the LBFC "the power and duty to perform ... all duties and functions relating to the study of the revenues, expenditures and fiscal problems of the Commonwealth, its officers, boards, committee, commissions, institutions, and other State agencies." As you know, studying fiscal problems involves more than a mere look at budget numbers and covers broader efficiency and effectiveness issues, as well as transparency and accountability to taxpayers. Review of performance helps identify wasteful processes and practices which need to be eliminated, and if gone unchecked, are hindrances to the efficient operation of state programs and the good stewardship of public resources. As such, the LBFC examining efficiency and effectiveness issues in the context of the state's handling of death certificates is certainly an "official duty" authorized by LBFC's enabling act.
You also express concern that HR 1087, as a single chamber resolution, cannot supersede the statutory provisions of the VSL. I agree; however, this is not the situation. HR 1087 merely directs the LBFC's statutory authority set forth above—it does not expand it. Further, the LBFC, as a bicameral, bipartisan legislative service agency, does not act solely on the authority of a single chamber's resolution. In such cases, it is the officers of the LBFC—one from each of the four caucuses—who approve moving forward with a study set forth by a resolution, as they are authorized to do by statute. These votes to adopt a study are made at public meetings and in accordance with Sunshine laws. Therefore, the LBFC's request to review death certificates is directly related to its official statutory duties to undertake all duties and functions relating to the study of the potential improper, inaccurate, and inconsistent reporting of COVID-related deaths to DOH. If not obstructed, this study can help identify inefficiencies and lead to recommendations to promote "economy in the government of the Commonwealth."

III. Research

Last, you also conclude that the LBFC's work related to HR 1087 is not "research" under VSL Section 805's research exception. You conclude Section 805 is not applicable because the LBFC is "not an entity established for the purpose of conducting research relating to vital statistics records or causes or manners of death." To be clear, the VSL does not require an entity to be "an entity established for the purpose of conducting research"; that is language you added. The VSL allows DOH to permit the use of vital statistics "for research". "Research" generally refers to "the systematic investigation into and study of materials and sources to establish facts and reach new conclusions." That is what the LBFC does and has done for more than 60 years. As such, the LBFC is clearly an entity that conducts research, i.e., studying, reviewing, and analyzing.

In closing, LBFC staff should be granted access to review death certificates pursuant to either or both Sections 805 and 806 of the VSL. The LBFC's role in the legislative process is to help ensure proper accountability and stewardship of public funds and resources, find ways to improve government, identify critical issues to protect public resources, and tighten government control systems. Without

access to death records—as is statutorily allowed for—the LBFC's statutory role and obligation is being obstructed.

Sincerely,

Rick K. Jones
Counsel
Legislative Budget & Finance Committee
400A Finance Building
Harrisburg, PA 17105
717-783-1600
rjones@palbfc.us

[1] The Metropolitan Transportation Authorities' Law 74 Pa CS 1701, which you also cite, takes a similar view by expressly excluding the legislature from its definition of "Government agency." Here again, this "carve out" shows the need to have express exclusion language to be able to conclude that the legislature is not intended to be within the definition of the government.

Appendix D - DOH Response to this Report

COMMONWEALTH OF PENNSYLVANIA
OFFICE OF THE SECRETARY OF HEALTH

November 3, 2021

Patricia A. Berger, Esq.
Executive Director
Legislative Finance and Budget Committee
P.O. Box 8737
Harrisburg, PA 17105

Dear Ms. Berger:

Please accept this correspondence as the Pennsylvania Department of Health's (Department) formal response to the Legislative Finance and Budget Committee's (LBFC) confidential draft report titled "A Report in Response to HR 1087 of 2020" developed pursuant to House Resolution 1087 of 2020 (HR 1087), which was initially submitted to the Department on May 20, 2021, and re-submitted as revised on June 7, 2021 and on September 28, 2021 (Report). While the Department recognizes that LBFC has addressed the majority of issues raised by the Department during its initial reviews, the Department has determined a formal written response is still warranted to provide additional clarity on the Department's legal analysis related to the Vital Statistics Law of 1953 (VSL)[1].

At the outset, the Department would like to thank LBFC and its staff for their work on this Report and for its recognition of the Department's notable accomplishments and efforts before and during the COVID-19 pandemic relating to death registration and reporting. Specifically, the Department would like to thank LBFC for the time taken to understand the complexity and importance of properly reporting deaths to public health and to families and for confirming that the Department's process to identify and count COVID-19 deaths was sound and in accordance with national standards. Further, the Department thanks LBFC for recognizing the drastic improvements made under the Wolf Administration for timely reporting to the Centers for Disease Control and Prevention (CDC).

The Department finds the Report to be generally comprehensive, however it continues to have concerns with the legal analysis of the VSL and resulting alleged scope impairment as presented throughout the Report. To clarify, LBFC requested from the Department redacted copies of 100 death certificates of persons whose deaths were attributed to COVID-19. After careful analysis, the Department determined that it was not authorized by law to disclose the requested records to LBFC and provided a written explanation of that determination (Report, Appendix B). To summarize, the VSL favors privacy and limits access to vital records, unless an entity meets the limited statutory exceptions. In this matter, a legislative budget and finance committee, whose statutory duty is to review information concerning the budget and expenditures, including the current condition of State funds and appropriations, does not meet the VSL statutory exceptions as an agency of government that is conducting an official duty and, further, is not an entity engaged in the conduct of research relating to vital statistics records.

[1] 35 P.S. §§ 450.101-450.1003.

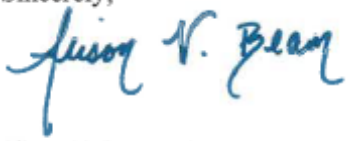
SECRETARY OF HEALTH
625 Forster Street | Health & Welfare Building 8th Floor West | Harrisburg, PA 17120 | 717.787.9857 | www.health.pa.gov

After thorough review of statutory definitions related to "agency of government" and "government agency," the Department determined that the General Assembly, a separate branch of government, is not included within the definition of "government agency," as statutorily defined. Distinctively, government agencies, as creatures of statute, are defined as executive agencies and local government. The definition of "government agency" is generally consistent across Commonwealth statutes and includes executive agencies and local government: specifically, "Commonwealth agency," "political subdivision," and "municipal or other local authority."[2] Importantly, none of these definitions of "government agency" includes the General Assembly or the legislature or its agencies.[3] For this reason, the Department cannot conclude that LBFC would be included in the common and approved usage of "agency of government" under the VSL. As such, the Department is prohibited by law from providing access to the requested vital statistic records.

Despite these legal provisions under the VSL, the Department collaborated with LBFC to establish an alternate solution to assist LBFC in the drafting of the Report while still complying with state and federal laws.

Throughout the COVID-19 pandemic, the Department has collected, analyzed, and published extraordinary levels of public health data. Professional statisticians, epidemiologists, physicians, data scientists, laboratorians, and public health experts within the Department have worked tirelessly to ensure these data, and the underlying reporting processes, are accurate in an effort to provide transparency and accountability for all Pennsylvanians. The Department worked closely with LBFC to support its drafting of the Report and is pleased to see the result will largely serve as a great educational tool for the General Assembly and the public.
The Department believes that Pennsylvanians have a right to accurate and concise data and information related to the COVID-19 pandemic response. Again, we appreciate the time and effort LBFC dedicated to this shared goal in developing this report.

Sincerely,



Alison V. Beam, JD
Acting Secretary of Health

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[2] *See* 23 Pa.C.S. § 4302; 42 Pa.C.S. § 102; 62 Pa.C.S. § 3102; and 74 Pa.C.S. § 1701.
[3] *See also* Logan Greens Cmty. Ass'n. Inc. v. Church Reserve. LLC, 1819 C.D. 2012, 2013 WL 5302578, at *3 (Pa.Cmwlth. Sept. 20, 2013) (General Assembly not a "government agency" when determining whether a portion of the Planned Community Act amounted to a government agency decision under the Permit Extension Act).